

Adverse events reported to Health Canada and received under Federal government Access to Information Act on March 25, 2002.

These vaccines were administered to MARTIN, born with severe hydronephrosis, pyeloplasty (2 ½ Mos.) and left nephrectomy (3 ½ Mos.) who is now ANAPHYLACTIC TO PEANUTS, NUTS, EGGS, MILK, KIWI, SESAME and LATEX and suffers from eczema.

Dec. 29/93

| | | |
|----------------|---------------|---|
| DPT-P 24008-11 | exp. June '94 | 49 adverse events (1 death, 2 seizures/convulsions) |
| Hib 3A0896 | exp. June '94 | 42 adverse events (4 seizures/convulsions) |

March 1/94

| | | |
|-----------------|---------------|--|
| DPT-P 24009-11 | exp. Nov. '94 | 76 adverse events (3 seizures/convulsions) |
| Hibtitre 3J0158 | exp. Nov. '94 | 6 adverse events (1 seizure/convulsion) |

April 27/94

| | | |
|-----------------|---------------|---|
| DPT-P 24010-11 | exp. Nov. '94 | 111 adverse events (8 seizures/convulsions) |
| Hibtitre 3C0629 | exp. July '94 | 21 adverse events (2 seizures/convulsions) |

No MMR given due to allergy to egg protein thank God

June 1/95

| | | |
|---|---------------|--|
| 5 doses combined in one syringe – "PENTA" | | |
| DPT-P 24017-11 | exp. June '96 | 664 adverse events (34 seizures/convulsions) |
| Act-Hib K0421 | exp. Apr. '96 | 6 adverse events |

TOTAL ADVERSE
REACTIONS REPORTED 975

The reactions, attached, include: death, seizure/convulsion, dysopnoae, speech disorder, allergic reaction, adenopathy, hypotonic-hyporesponsive episode, severe pain and/or swelling, screaming episode, hypokinesia, persistent crying, severe vomiting and/or diarrhea, lethargy, fever, cyanoisis, rashes, eczema, pneumonia, lymphocytosis, sterile abcess/nodule/necrosis, infective abcess, tachycardia, gait abnormal, ataxia, bulging fontanelle, sepsis, vaso-vagal reaction, tremor, arthritis, cellulitis, bradyapnoea, delirium, reduced consciousness, shaking, somnolence, anaphylaxis, apnoae, encephalopathy, asthma, injection site reaction, shortness of breath, and confusion.

Manufacturer DPT-P and Act-Hib: Connaught Laboratories (now Aventis Pasteur). Wyeth Ayerst may have manufactured the Hib and Hibtitre, but I was told that their "records only go as far back as 1997."

Compiled by outraged mother Rita Hoffman ~~XXXXXXXXXX~~

~~Revised with my participation~~
This data remains UNADDRESSED BY ALL LEVELS OF
GOVERNMENT AND ALL HEALTH OFFICIALS

September 9, 2003

April 28, 2004

June 16, 2005

March 5/2007

May 30/
2008.
May 6, 2013

DPT Polio
Lot. 24008-11

49 adverse events

1 death
2 seizures/convulsions

Expiry
June
1994

* CAVEAT: The vast majority of reports on which this summary is based are submitted by health practitioners. Each report represents the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports to the Population and Public Health Branch has not been reviewed as to cause and effect relationship by Population and Public Health Branch scientists. Only a small proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse events. Reports submitted by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data will be used only for your personal use or within your immediate organization.

Please note the following:

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Adverse events reported following use of vaccine batch # 24008-11

| V_Number | Age | Age Unit | Sex | Outcome | Adverse event |
|--|-----|----------|--------|-----------|---|
| ff | | | | | |
| V931648 | 2 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V931954 | 4 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE DYSPOEA LETHARGY |
| V932309 | 4 | Years | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED HYPOTONIC-HYPORESPONSIVE EPISODE SEVERE VOMITING AND/OR DIARRHEA |
| V932481 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V932697 | 2 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V932704 | 2 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V933319 | 18 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V933320 | 18 | Months | Male | Recovered | SEVERE VOMITING AND/OR DIARRHEA |
| V933335 | 13 | Months | Male | Recovered | FEVER 37.5 - 38.9 FEVER - TEMPERATURE NOT RECORDED SEVERE VOMITING AND/OR DIARRHEA SEVERE PAIN AND/OR SWELLING |
| V933423 | 2 | Years | Female | Recovered | FEVER 37.5 - 38.9 SEVERE PAIN AND/OR SWELLING ADENOPATHY |
| V933877 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA |
| V934200 | 5 | Years | - | Recovered | STERILE ABCESS/NODULE/NECROSIS |
| V934315 | 20 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED SCREAMING EPISODE/PERSISTENT CRYING |
| V934319 | 5 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V934383 | 12 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V934400 | 6 | Months | Female | Recovered | CONVULSION/SEIZURE FEVER 37.5 - 38.9 |
| V934574 | 4 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE CONVULSION/SEIZURE FEVER - TEMPERATURE NOT RECORDED |

Adverse events reported following use of vaccine batch # 24008-11

| V_Number | Age | Age Unit | Sex | Outcome | Adverse event |
|--|-----|----------|--------|-----------|---|
| ff | | | | | |
| V934574 | 4 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING OPISTHOTONOS |
| V938727 | 4 | Years | Male | - | FEVER - TEMPERATURE NOT RECORDED HALLUCINATION |

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| | | | | | |
|---------|----|--------|--------|---|-------------------------------------|
| V938739 | 16 | Months | Male | - | FEVER - TEMPERATURE NOT RECORDED |
| V938741 | 4 | Months | Male | - | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V938745 | 6 | Years | Male | - | FEVER 37.5 - 38.9 |
| V938747 | 7 | Months | Male | - | ALLERGIC REACTION |
| | | | | | ALLERGIC REACTION |
| | | | | | RASHES |
| V938748 | 5 | Months | Male | - | FEVER 39.0 - 40.4 |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | RASHES |
| V938750 | 5 | Years | Male | - | FEVER 37.5 - 38.9 |
| V938760 | 2 | Months | Male | - | FEVER - TEMPERATURE NOT RECORDED |
| V938762 | 18 | Months | Female | - | FEVER 39.0 - 40.4 |
| V938763 | 18 | Months | Male | - | STERILE ABCESS/NODULE/NECROSIS |
| V938765 | 6 | Months | Female | - | FEVER 37.5 - 38.9 |
| V938767 | 2 | Months | Male | - | SEVERE PAIN AND/OR SWELLING |
| V938768 | 6 | Months | Male | - | SCREAMING EPISODE/PERSISTENT CRYING |
| V938770 | 5 | Years | Male | - | SEVERE PAIN AND/OR SWELLING |
| V938772 | 5 | Years | Male | - | SEVERE PAIN AND/OR SWELLING |
| V938776 | 3 | Months | Male | - | FEVER 39.0 - 40.4 |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V938777 | 2 | Months | Male | - | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| V938779 | 4 | Months | Male | - | RASHES |
| V938780 | 4 | Years | Female | - | SEVERE PAIN AND/OR SWELLING |

Adverse events reported following use of vaccine batch # 24008-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V938785 | 4 | Months | Male | - | SEVERE VOMITING AND/OR DIARRHEA |
| V940059 | 2 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V940180 | 3 | Months | Female | Recovered | FEVER 39.0 - 40.4 |
| V940678 | 3 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V940964 | 2 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V941834 | 8 | Months | Male | Fatal | FEVER 39.0 - 40.4 |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| | | | | | BRADYCARDIA |
| V948007 | 3 | Months | Male | - | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V948011 | 2 | Months | Female | - | FEVER 39.0 - 40.4 |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| V948038 | 5 | Years | Female | - | ARTHRALGIA/ARTHRITIS |
| V948039 | 3 | Months | Male | - | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| V9591790 | 5 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9891052 | 2 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |

H7b Lot 3A0896 42 adverse 4 convulsions/seizure events
exp. June 1994

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Adverse events reported following use of vaccine batch # 3A0896

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V931648 | 2 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V932709 | 2 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V932716 | 9 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V932791 | 7 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V932841 | 2 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V932912 | 20 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V932922 | 8 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V932923 | 19 | Months | Female | Recovered | INJECTION SITE REACTION |
| V932934 | 23 | Months | Female | Recovered | IRRITABILITY |
| V933026 | 5 | Months | Female | Recovered | CONVULSION/SEIZURE |
| V933035 | 2 | Months | Male | Recovered | ALLERGIC REACTION |
| V933043 | 3 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V933256 | 4 | Years | Male | Recovered | ARTHRALGIA/ARTHRITIS |
| V933326 | 2 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V933333 | 6 | Months | Male | Recovered | ALLERGIC REACTION |
| V933355 | 6 | Months | Female | Recovered | CONVULSION/SEIZURE |
| V933420 | 2 | Years | Male | Recovered | FEVER 37.5 - 38.9 |
| V933449 | 7 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V933626 | 7 | Months | Male | Recovered | ARTHRALGIA/ARTHRITIS |
| V933652 | 18 | Months | Female | Recovered | ALLERGIC REACTION |

Adverse events reported following use of vaccine batch # 3A0896

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V933652 | 18 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V933877 | 4 | Months | Female | Recovered | ALLERGIC REACTION |
| V934253 | 2 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V934267 | 6 | Months | Female | Recovered | SEVERE VOMITING AND/OR DIARRHEA |
| V934276 | 5 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V934286 | 9 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |

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| | | | | |
|---------|----|--------|--------|-----------|
| V934295 | 9 | Months | Female | Recovered |
| V934299 | 6 | Months | Male | Recovered |
| V934618 | 4 | Months | Male | Recovered |
| V940063 | 18 | Months | Female | Recovered |
| V940067 | 2 | Months | Female | Recovered |
| V940194 | 2 | Months | Female | Recovered |
| V940575 | 7 | Months | Female | Recovered |
| V941387 | 6 | Months | Male | Recovered |
| V941389 | 4 | Months | Male | Recovered |
| V941393 | 18 | Months | Female | Recovered |
| V941394 | 4 | Months | Male | Recovered |
| V942135 | 5 | Months | Female | Recovered |
| V942266 | 6 | Months | Male | Recovered |
| V948050 | 4 | Months | Female | - |
| V950378 | 5 | Months | Male | Recovered |
| V960081 | 8 | Months | Female | Recovered |

FEVER 37.5 - 38.9
 FEVER 37.5 - 38.9
 SCREAMING EPISODE/PERSISTENT CRYING
 FEVER 39.0 - 40.4
 SCREAMING EPISODE/PERSISTENT CRYING
 FEVER - TEMPERATURE NOT RECORDED
 SCREAMING EPISODE/PERSISTENT CRYING
 HYPOTONIC-HYPORESPONSIVE EPISODE
 FEVER 37.5 - 38.9
 FEVER 37.5 - 38.9
 SCREAMING EPISODE/PERSISTENT CRYING
 FEVER 37.5 - 38.9
 SCREAMING EPISODE/PERSISTENT CRYING
 FEVER 37.5 - 38.9
 HYPOTONIC-HYPORESPONSIVE EPISODE
 DYSPNEA
 TACHYCARDIA
 CONVULSION/SEIZURE
 CONVULSION/SEIZURE
 FEVER 37.5 - 38.9

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DPT Polio Lot 24009-11

Exp. Nov. 1994

76 adverse events

3 convulsions/seizures

Adverse events reported following use of vaccine batch # 24009-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V933869 | 5 | Years | Male | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA CONFUSION |
| V933892 | 2 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V934274 | 6 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED SCREAMING EPISODE/PERSISTENT CRYING SEVERE PAIN AND/OR SWELLING |
| V934541 | 18 | Months | Female | Recovered | FEVER 39.0 - 40.4 |
| V934554 | 4 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V934558 | 18 | Months | Female | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING |
| V938771 | 6 | Months | Male | - | FEVER 39.0 - 40.4 RASHES |
| V938784 | 6 | Months | Male | - | FEVER 37.5 - 38.9 |
| V940006 | 4 | Years | Male | Recovered | ALLERGIC REACTION |
| V940160 | 4 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V940167 | 18 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V940204 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING |
| V940207 | 18 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V940210 | 3 | Months | Male | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING |
| V940272 | 2 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V940327 | 4 | Years | Male | Recovered | FEVER 39.0 - 40.4 |
| V940456 | 2 | Months | - | Recovered | FEVER 37.5 - 38.9 |
| V940618 | 2 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V940625 | 6 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE SCREAMING EPISODE/PERSISTENT CRYING |
| V940638 | 6 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |

Adverse events reported following use of vaccine batch # 24009-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V940986 | 5 | Years | Male | Recovered | ASTHMA ALLERGIC REACTION |
| V941168 | 4 | Months | Female | Recovered | STERILE ABCESS/NODULE/NECROSIS |
| V941387 | 6 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V941390 | 2 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V941397 | 19 | Months | Female | Recovered | FEVER 39.0 - 40.4 |
| V941399 | 5 | Months | Female | Recovered | FEVER 39.0 - 40.4 |
| V941401 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V941402 | 5 | Months | Male | Recovered | FEVER 39.0 - 40.4 HYPOTONIC-HYPORESPONSIVE EPISODE IRRITABILITY ALLERGIC REACTION SHORTNESS OF BREATH |
| V941408 | 2 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V941427 | 5 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V941444 | 5 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V941459 | 3 | Months | Female | Recovered | FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE SEVERE PAIN AND/OR SWELLING |
| V941492 | 6 | Years | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V941517 | 5 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V941801 | 4 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED HYPOTONIC-HYPORESPONSIVE EPISODE SCREAMING EPISODE/PERSISTENT CRYING |
| V941816 | 2 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V941873 | 5 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V941902 | 3 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED SCREAMING EPISODE/PERSISTENT CRYING |
| V941956 | 2 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V941987 | 20 | Months | Male | Recovered | FEVER 39.0 - 40.4 SCREAMING EPISODE/PERSISTENT CRYING |

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Adverse events reported following use of vaccine batch # 24009-11

| V_Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V942409 | 4 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V942426 | 20 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V942504 | 4 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V942516 | 2 | Months | Male | Recovered | ALLERGIC REACTION |
| | | | | | RASH-EXZEMA |
| | | | | | FEVER 37.5 - 38.9 |
| | | | | | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V942688 | 5 | Years | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | CELLULITIS |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| V943155 | 12 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | CONVULSION/SEIZURE |
| V948010 | 18 | Months | Female | - | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| V948012 | 2 | Months | Female | - | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| V948014 | 4 | Years | Male | - | FEVER 37.5 - 38.9 |
| | | | | | STERILE ABCESS/NODULE/NECROSIS |
| V948018 | 18 | Months | Male | - | INJECTION SITE REACTION |
| V948025 | 18 | Months | Female | - | FEVER 37.5 - 38.9 |
| V948027 | 19 | Months | Male | - | FEVER 39.0 - 40.4 |
| V948028 | 5 | Years | Female | - | SEVERE PAIN AND/OR SWELLING |
| V948029 | 9 | Years | Female | - | SEVERE PAIN AND/OR SWELLING |
| V948034 | 4 | Years | Male | - | IRRITABILITY |
| V948054 | 5 | Months | Female | - | FEVER 37.5 - 38.9 |
| V948055 | 2 | Months | Female | - | FEVER 37.5 - 38.9 |
| V948056 | 4 | Months | Female | - | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | RASHES |

Adverse events reported following use of vaccine batch # 24009-11

| V_Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--------------------------------------|
| V948057 | 2 | Months | Male | - | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V948058 | 5 | Years | Female | - | SEVERE PAIN AND/OR SWELLING |
| V948059 | 4 | Months | Male | - | SEVERE PAIN AND/OR SWELLING |
| V948061 | 2 | Months | Male | - | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | FEVER 37.5 - 38.9 |
| | | | | | ENCEPHALOPATHY |
| V948065 | 23 | Months | Female | - | CONVULSION/SEIZURE |
| V948089 | 3 | Months | Female | - | CONVULSION/SEIZURE |
| V948111 | 19 | Months | Male | - | FEVER 39.0 - 40.4 |
| | | | | | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| V948130 | 5 | Years | Male | - | INFECTIVE ABCESS |
| V950157 | 6 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951782 | 6 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V958090 | 3 | Months | Male | - | SEVERE PAIN AND/OR SWELLING |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V9590619 | 6 | Months | Male | Recovered | ALLERGIC REACTION |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V9591409 | 4 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9591453 | 5 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9700429 | 3 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| | | | | | FEVER 37.5 - 38.9 |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V9700435 | 4 | Months | Male | Recovered | ALLERGIC REACTION-RESPIRATORY & SKIN |
| V9702985 | 5 | Years | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| | | | | | FEVER 37.5 - 38.9 |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |

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Adverse events reported following use of vaccine batch # 24009-11

| V_Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|-------|--------|-----------|--|
| V9890790 | 6 | Years | Female | Recovered | INJECTION SITE REACTION MALAISE SOMNOLENCE FEVER - TEMPERATURE NOT RECORDED |

Expiry Nov 1994

6 adverse events

1 Convulsion/seizure

Hib-tite

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Adverse events reported following use of vaccine batch # 3J0158

| V_Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|------|-----|---------|---------------|
|----------|-----|------|-----|---------|---------------|

| | | | | | |
|---------|----|--------|--------|-----------|---|
| V938765 | 6 | Months | Female | - | FEVER 37.5 - 38.9 |
| V942710 | 2 | Months | Male | Recovered | FEVER 39.0 - 40.4 |
| V948010 | 18 | Months | Female | - | SCREAMING EPISODE/PERSISTENT CRYING SEVERE PAIN AND/OR SWELLING |
| V948061 | 2 | Months | Male | - | FEVER 37.5 - 38.9 ENCEPHALOPATHY |
| V948092 | 4 | Months | Male | - | CONVULSION/SEIZURE FEVER 39.0 - 40.4 |
| V958010 | 18 | Months | Female | - | SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING FEVER 39.0 - 40.4 ARTHRALGIA/ARTHRITIS |

DPT Polio

exp. November 1994

111 adverse events

8 convulsions/seizures

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Adverse events reported following use of vaccine batch # 24010-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V938781 | 18 | Months | Female | - | FEVER 37.5 - 38.9 |
| V940128 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V940212 | 18 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V940577 | 18 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V940590 | 18 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V940591 | 18 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V940617 | 18 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V940620 | 18 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V940621 | 19 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V940624 | 18 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V940631 | 18 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V940634 | 18 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V940635 | 18 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V940679 | 11 | Months | Male | Recovered | FEVER 39.0 - 40.4 |
| V940680 | 4 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V940898 | 7 | Months | Male | Recovered | CONVULSION/SEIZURE |
| V940904 | 18 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V940905 | 18 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V940911 | 5 | Years | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V940932 | 7 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V940938 | 3 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V940949 | 19 | Months | Female | Recovered | SEVERE VOMITING AND/OR DIARRHEA |
| V940972 | 18 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V941025 | 18 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V941026 | 18 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V941031 | 2 | Months | Female | Recovered | LETHARGY |
| V941167 | 4 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V941169 | 5 | Months | Male | Recovered | STERILE ABCESS/NODULE/NECROSIS |

Adverse events reported following use of vaccine batch # 24010-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V941169 | 5 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V941170 | 2 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V941171 | 4 | Years | Female | Recovered | FEVER 39.0 - 40.4 |
| V941404 | 5 | Years | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V941406 | 18 | Months | Female | Recovered | SEVERE VOMITING AND/OR DIARRHEA |
| V941416 | 20 | Months | Female | Recovered | ARTHRALGIA/ARTHRITIS |
| V941419 | 5 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| | | | | | RASH |
| | | | | | CONVULSION/SEIZURE |
| | | | | | FEVER 37.5 - 38.9 |

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| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|------------|--|
| V941441 | 8 | Months | Female | Recovering | SEVERE VOMITING AND/OR DIARRHEA FEVER 37.5 - 38.9 |
| V941442 | 5 | Years | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING HYPOTONIC-HYPORESPONSIVE EPISODE ARTHRALGIA/ARTHRITIS |
| V941455 | 5 | Years | Female | Recovered | SEVERE VOMITING AND/OR DIARRHEA FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING RASHES |
| V941457 | 18 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V941477 | 23 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V941485 | 4 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V941518 | 6 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V941551 | 4 | Years | Male | Recovered | FEVER 37.5 - 38.9 CONVULSION/SEIZURE |
| V941783 | 2 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V941792 | 6 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V941793 | 3 | Years | Female | Recovered | CONVULSION/SEIZURE |
| V941798 | 5 | Months | Male | Recovered | FEVER 39.0 - 40.4 |

Adverse events reported following use of vaccine batch # 24010-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V941800 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING |
| V941811 | 4 | Months | Male | Recovered | FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE SCREAMING EPISODE/PERSISTENT CRYING |
| V941814 | 7 | Months | Male | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA |
| V941818 | 4 | Months | Male | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA |
| V941819 | 4 | Months | Male | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA |
| V941822 | 5 | Years | Male | Recovered | FEVER 39.0 - 40.4 SEVERE VOMITING AND/OR DIARRHEA |
| V941898 | 8 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V941925 | 5 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED SCREAMING EPISODE/PERSISTENT CRYING |
| V941928 | 6 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING |
| V941945 | 5 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V941957 | 5 | Years | Male | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA |
| V942140 | 2 | Months | Female | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING |
| V942192 | 4 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V942195 | 5 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V942203 | 5 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V942252 | 18 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V942276 | 6 | Months | Male | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING |

Adverse events reported following use of vaccine batch # 24010-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V942322 | 2 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V942425 | 5 | Months | Male | Recovered | SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING ALLERGIC REACTION |
| V942441 | 19 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V942442 | 3 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V942835 | 2 | Months | Female | Recovered | INJECTION SITE REACTION |
| V942858 | 4 | Years | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING |
| V943137 | 20 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED |

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| | | | | | |
|---------|----|--------|--------|---|-------------------------------------|
| V948023 | 5 | Years | Female | - | SEVERE PAIN AND/OR SWELLING |
| V948035 | 4 | Months | Male | - | SCREAMING EPISODE/PERSISTENT CRYING |
| V948064 | 2 | Months | Female | - | SEVERE PAIN AND/OR SWELLING |
| V948066 | 6 | Years | Male | - | SEVERE PAIN AND/OR SWELLING |
| V948068 | 19 | Months | Male | - | SEVERE VOMITING AND/OR DIARRHEA |
| V948071 | 4 | Years | Male | - | FEVER 37.5 - 38.9 |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| V948072 | 4 | Years | Male | - | FEVER 37.5 - 38.9 |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| V948073 | 8 | Months | Male | - | SCREAMING EPISODE/PERSISTENT CRYING |
| V948076 | 20 | Months | Female | - | FEVER 37.5 - 38.9 |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| | | | | | RASHES |
| V948077 | 4 | Months | Male | - | FEVER 37.5 - 38.9 |
| | | | | | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V948081 | 2 | Months | Male | - | ALLERGIC REACTION |
| V948082 | 2 | Months | Female | - | FEVER 37.5 - 38.9 |
| | | | | | CONVULSION/SEIZURE |
| V948083 | 9 | Years | Female | - | FEVER - TEMPERATURE NOT RECORDED |

Adverse events reported following use of vaccine batch # 24010-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V948083 | 9 | Years | Female | - | RASHES |
| V948088 | - | - | Male | - | SCREAMING EPISODE/PERSISTENT CRYING |
| V948090 | 18 | Months | Male | - | SCREAMING EPISODE/PERSISTENT CRYING |
| V948092 | 4 | Months | Male | - | FEVER 39.0 - 40.4 |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| V948096 | 18 | Months | Female | - | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V948097 | 5 | Years | Male | - | SEVERE PAIN AND/OR SWELLING |
| | | | | | FEVER 37.5 - 38.9 |
| | | | | | ARTHRALGIA/ARTHRITIS |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| V948098 | 5 | Years | Female | - | SEVERE PAIN AND/OR SWELLING |
| | | | | | FEVER 37.5 - 38.9 |
| V948102 | 18 | Months | Male | - | SEVERE PAIN AND/OR SWELLING |
| V948103 | 5 | Years | Male | - | SEVERE PAIN AND/OR SWELLING |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| V948113 | 23 | Months | Male | - | RASHES |
| | | | | | FEVER 37.5 - 38.9 |
| V948116 | 6 | Years | Female | - | SEVERE PAIN AND/OR SWELLING |
| | | | | | FEVER 37.5 - 38.9 |
| | | | | | CONVULSION/SEIZURE |
| V948117 | 2 | Months | Male | - | SCREAMING EPISODE/PERSISTENT CRYING |
| V948120 | 2 | Months | Female | - | SCREAMING EPISODE/PERSISTENT CRYING |
| V948134 | 4 | Years | Male | - | FEVER 37.5 - 38.9 |
| V948150 | 4 | Years | Female | - | SEVERE PAIN AND/OR SWELLING |
| V948152 | 5 | Years | Female | Recovered | FEVER 39.0 - 40.4 |
| V948153 | 18 | Months | Male | - | RASHES |
| V948162 | 6 | Years | Male | - | FEVER 37.5 - 38.9 |
| | | | | | SEVERE PAIN AND/OR SWELLING |

Adverse events reported following use of vaccine batch # 24010-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V948178 | 4 | Years | Female | - | FEVER 37.5 - 38.9 |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| V948264 | 3 | Months | Female | - | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V958012 | 5 | Years | Female | - | FEVER 39.0 - 40.4 |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| | | | | | CONVULSION/SEIZURE |
| V9590889 | 5 | Years | Male | Recovered | ASTHMA |
| V9591324 | 7 | Months | Male | Recovered | INJECTION SITE REACTION |

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| | | | | |
|----------|----|--------|--------|-----------|
| V9591466 | 4 | Years | Female | Recovered |
| V9700445 | 2 | Years | Female | Recovered |
| V9703094 | 19 | Months | Female | Recovered |
| V9990542 | 3 | Years | Male | Recovered |

FEVER 37.5 - 38.9
SEVERE PAIN AND/OR SWELLING
FEVER - TEMPERATURE NOT RECORDED
SEVERE PAIN AND/OR SWELLING-PAST JOINTS
(*) CONVULSION/SEIZURE-AFEBRILE
SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO
IRRITABILITY
DROWSINESS
FLUSHING

4

Hib titre

[21 adverse events]

2 convulsions/
Seizures

Lot 3C0629 exp. July 1994

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Adverse events reported following use of vaccine batch # 3C0629

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V931773 | 73 | Years | - | Recovered | ARTHRALGIA/ARTHRITIS |
| V932804 | 3 | Months | Female | Recovered | RASHES |
| V932890 | 5 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V934056 | 12 | Months | Female | Recovered | APNOEA |
| V934278 | 5 | Months | Female | Recovered | CONVULSION/SEIZURE |
| V938777 | 2 | Months | Male | - | FEVER 37.5 - 38.9 |
| V940157 | 7 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V941169 | 5 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V941381 | 19 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V941390 | 2 | Months | Male | Recovered | SEVERE VOMITING AND/OR DIARRHEA |
| V941397 | 19 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V941399 | 5 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V941401 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V941408 | 2 | Months | Female | Recovered | STERILE ABCESS/NODULE/NECROSIS |
| V941801 | 4 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V941806 | 18 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| | | | | | CONVULSION/SEIZURE |
| | | | | | IRRITABILITY |
| | | | | | PALLOR |
| | | | | | CYANOSIS |
| | | | | | HYPOTONIC-HYPORESPONSIVE EPISODE |
| | | | | | FEVER 39.0 - 40.4 |
| | | | | | FEVER 39.0 - 40.4 |
| | | | | | FEVER 37.5 - 38.9 |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | HYPOTONIC-HYPORESPONSIVE EPISODE |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | ALLERGIC REACTION |
| | | | | | RASHES |

Adverse events reported following use of vaccine batch # 3C0629

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V941810 | 7 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V942141 | 2 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |

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V948007 3 Months Male -
V948057 2 Months Male -
V9590270 7 Months Female Recovered

HYPOTONIC-HYPORESPONSIVE EPISODE
FEVER - TEMPERATURE NOT RECORDED
SCREAMING EPISODE/PERSISTENT CRYING
SEVERE PAIN AND/OR SWELLING
FEVER 39.0 - 40.4

3

Child received
vaccine June 1, 1995

PENTA-5 in 1 combined with Act Hib K0421 Expiry Date June 96 23 pages
664 Adverse Events Reported

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34 SEIZURES/CONVULSIONS

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Adverse events reported following use of vaccine batch # 24017-11

| V_Number | Age | Age Unit | Sex | Outcome | Adverse event |
|----------|-----|----------|--------|-----------|--|
| V950335 | 5 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V950336 | 2 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V950380 | 22 | Months | Female | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING SEVERE PAIN AND/OR SWELLING |
| V950529 | 4 | Years | Male | Recovered | FEVER 37.5 - 38.9 INSOMNIA IRRITABILITY DYSPNOEA SPEECH DISORDER SEVERE PAIN AND/OR SWELLING ADENOPATHY ALLERGIC REACTION |
| V950531 | 4 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V950537 | 5 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V950538 | 5 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V950539 | 5 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V950540 | 5 | Years | Female | Recovered | INJECTION SITE PAIN |
| V950648 | 2 | Months | Male | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA SEVERE PAIN AND/OR SWELLING |
| V950727 | 5 | Years | Female | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA |
| V950822 | 11 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V950929 | 4 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V950936 | 7 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED HYPOTONIC-HYPORESPONSIVE EPISODE |
| V950938 | 7 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V950939 | 2 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V950940 | 4 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |

Adverse events reported following use of vaccine batch # 24017-11

| V_Number | Age | Age Unit | Sex | Outcome | Adverse event |
|----------|-----|----------|--------|-----------|---|
| V950942 | 18 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED RASHES |
| V950943 | 7 | Months | Female | Recovered | FEVER 37.5 - 38.9 CONVULSION/SEIZURE |
| V950944 | 4 | Years | - | Recovered | FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING |

20

1

| | | | | | |
|---------|----|--------|--------|-----------|-------------------------------------|
| V950968 | 5 | Years | Male | Recovered | ALLERGIC REACTION |
| V950970 | 2 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V950971 | 3 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V950972 | 4 | Years | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V950981 | 2 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| | | | | | HYPOTONIC-HYPORESPONSIVE EPISODE |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V951006 | 6 | Years | Male | Recovered | FEVER 39.0 - 40.4 |
| V951029 | 6 | Years | Male | Recovered | INJECTION SITE REACTION |
| V951057 | 2 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951073 | - | - | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951077 | 2 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| | | | | | DYSPNOEA |
| V951100 | 22 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| | | | | | HYPOTONIC-HYPORESPONSIVE EPISODE |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V951103 | 4 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V951177 | 3 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V951180 | 2 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V951248 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | WHEEZING |
| | | | | | CHILLS |
| | | | | | ANOREXIA |
| | | | | | CROUP |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V951253 | 18 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V951265 | 2 | Years | Male | Recovered | ALLERGIC REACTION |
| V951276 | 23 | Months | Female | Recovered | ALLERGIC REACTION |
| V951315 | 5 | Years | Female | Recovered | FEVER 37.5 - 38.9 |
| V951316 | 5 | Years | Female | Recovered | ALLERGIC REACTION |
| V951317 | 6 | Years | Female | Recovered | INJECTION SITE REACTION |
| V951329 | 19 | Months | Female | Recovered | ALLERGIC REACTION |
| V951330 | 20 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V951331 | 19 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| | | | | | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | GAIT ABNORMAL |
| | | | | | TREMOR |
| | | | | | INJECTION SITE REACTION |
| V951334 | 5 | Months | Female | Recovered | LETHARGY |
| V951336 | 3 | Years | Female | Recovered | FEVER 37.5 - 38.9 |
| V951342 | 7 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V951347 | 4 | Months | Female | Recovered | RASHES |
| V951352 | 5 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V951356 | 5 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951360 | 18 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951367 | 2 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951369 | 4 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V951372 | 5 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V951373 | 19 | Months | Female | Recovered | ALLERGIC REACTION |
| | | | | | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| | | | | | FEVER 37.5 - 38.9 |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-----------------------------|
| V951374 | 19 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951385 | 19 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951414 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V951423 | 18 | Months | Female | Recovered | ALLERGIC REACTION |
| V951426 | 5 | Years | Male | Recovered | FEVER 37.5 - 38.9 |
| | | | | | SEVERE PAIN AND/OR SWELLING |

| | | | | | |
|---------|----|--------|--------|-----------|--|
| V951434 | 2 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V951443 | 2 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V951444 | 7 | Months | Male | Recovered | SEVERE VOMITING AND/OR DIARRHEA SEVERE PAIN AND/OR SWELLING ALLERGIC REACTION |
| V951461 | 2 | Years | Female | Recovered | FEVER 37.5 - 38.9 |
| V951477 | 4 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V951480 | 6 | Years | Male | Recovered | FEVER 37.5 - 38.9 HEADACHE LETHARGY <u>CONVULSION/SEIZURE</u> |
| V951490 | 18 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951528 | 6 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V951555 | 4 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V951602 | 2 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V951613 | 2 | Months | Male | Recovered | INJECTION SITE REACTION |
| V951614 | 8 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING HYPOTONIC-HYPORESPONSIVE EPISODE |
| V951615 | 5 | Months | Female | Recovered | INJECTION SITE REACTION |
| V951616 | 18 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V951617 | 19 | Months | Female | Recovered | INJECTION SITE REACTION |
| V951619 | 5 | Years | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V951623 | 5 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V951624 | 20 | Months | Male | Recovered | SEVERE VOMITING AND/OR DIARRHEA ALLERGIC REACTION |
| V951631 | 4 | Months | Male | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING |
| V951633 | 18 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V951633 | 18 | Months | Male | Recovered | SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING SEVERE PAIN AND/OR SWELLING |
| V951634 | 8 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951643 | 18 | Months | Female | Recovered | INJECTION SITE REACTION |
| V951649 | 2 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V951653 | 18 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951654 | 2 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951690 | 2 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951694 | 6 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V951698 | 8 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED SCREAMING EPISODE/PERSISTENT CRYING SEVERE PAIN AND/OR SWELLING |
| V951709 | 6 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V951711 | 6 | Months | Female | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING |
| V951712 | 20 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V951719 | 4 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING SCREAMING EPISODE/PERSISTENT CRYING ALLERGIC REACTION |
| V951720 | 5 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V951721 | 4 | Months | Female | Recovered | FEVER 39.0 - 40.4 |
| V951722 | 5 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V951724 | 6 | Months | Male | Recovered | FEVER 39.0 - 40.4 |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V951726 | 12 | Months | Male | Recovered | FEVER 37.5 - 38.9 IRRITABILITY CYANOSIS RASHES |
| V951727 | 18 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V951734 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 |

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| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V951736 | 5 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V951739 | 2 | Years | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V951748 | 5 | Months | Male | Recovered | PNEUMONIA |
| | | | | | LYMPHOCYTOSIS |
| | | | | | LETHARGY |
| | | | | | FEVER 37.5 - 38.9 |
| V951750 | 3 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V951760 | 7 | Months | Female | Recovered | SEVERE VOMITING AND/OR DIARRHEA |
| V951764 | 5 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | FEVER 37.5 - 38.9 |
| V951765 | 4 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| | | | | | FEVER 37.5 - 38.9 |
| V951769 | 5 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951787 | 7 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| V951789 | 2 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V951790 | 4 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V951796 | 4 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V951800 | 5 | Years | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| | | | | | ALLERGIC REACTION |
| V951806 | 5 | Years | Male | Recovered | INJECTION SITE REACTION |
| V951807 | 5 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951809 | 5 | Years | Male | Recovered | INJECTION SITE REACTION |
| V951816 | 18 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| V951818 | 4 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V951824 | 3 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951830 | 2 | Months | Female | Recovered | SEVERE VOMITING AND/OR DIARRHEA |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| V951833 | 6 | Months | Female | Recovered | SEVERE VOMITING AND/OR DIARRHEA |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V951837 | 5 | Years | Male | Recovered | INJECTION SITE REACTION |
| V951841 | 2 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V951851 | 5 | Years | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| | | | | | ALLERGIC REACTION |
| V951856 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V951857 | 2 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | HYPOTONIC-HYPORESPONSIVE EPISODE |
| | | | | | DYSPOEA |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| V951859 | 7 | Months | Male | Recovered | CONVULSION/SEIZURE |
| V951862 | 8 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | SEVERE PAIN AND/OR SWELLING |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V951863 | 2 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| V951869 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V951877 | 5 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| | | | | | FEVER 37.5 - 38.9 |

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| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V951879 | 5 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V951880 | 4 | Months | Female | Recovered | INJECTION SITE REACTION |
| V951909 | 6 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | FEVER 37.5 - 38.9 |
| | | | | | <u>CONVULSION/SEIZURE</u> |
| V951912 | 4 | Years | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V951913 | 4 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V951914 | 7 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | <u>CONVULSION/SEIZURE</u> |
| V951919 | 5 | Months | - | Recovered | PASHES |
| V951922 | 2 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| V951927 | 4 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V951945 | 19 | Months | Female | Recovered | ALLERGIC REACTION |
| V951967 | 2 | Months | Male | Recovered | |
| V951969 | 6 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V952007 | 6 | Months | Male | Recovered | PASHES |
| V952008 | 2 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| | | | | | ANAEMIA |
| | | | | | PALLOR |
| | | | | | APNOEA |
| | | | | | <u>CONVULSION/SEIZURE</u> |
| V952012 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V952013 | 2 | Months | Female | Recovered | INJECTION SITE REACTION |
| | | | | | PALLOR |
| | | | | | LETHARGY |
| | | | | | FEVER |
| | | | | | IRRITABILITY |
| V952014 | 4 | Months | Female | Recovered | FEVER 39.0 - 40.4 |
| V952017 | 4 | Months | Male | Recovered | FEVER 39.0 - 40.4 |
| V952019 | 5 | Years | Male | Recovered | PALLOR |
| | | | | | LETHARGY |
| | | | | | HEADACHE |
| | | | | | FAINTNESS |
| | | | | | ABDOMINAL PAIN |
| | | | | | <u>CONVULSION/SEIZURE</u> |
| V952020 | 2 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V952028 | 5 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V952032 | 18 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V952033 | 18 | Months | Female | Recovered | FEVER 39.0 - 40.4 |
| V952034 | 7 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V952034 | 7 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V952035 | 4 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V952036 | 2 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V952037 | 4 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V952039 | 4 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V952043 | 3 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| V952049 | 7 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V952065 | 5 | Months | Male | Recovered | SEVERE VOMITING AND/OR DIARRHEA |
| V952069 | 7 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | FEVER 37.5 - 38.9 |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V952073 | 2 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| | | | | | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V952076 | 4 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V952078 | 2 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | FEVER - TEMPERATURE NOT RECORDED |

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| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|------------|--|
| V952096 | 4 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING SEVERE PAIN AND/OR SWELLING FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE TACHYCARDIA SEPSIS IRRITABILITY |
| V952102 | 6 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING SCREAMING EPISODE/PERSISTENT CRYING SEVERE PAIN AND/OR SWELLING |
| V952103 | 4 | Months | Male | Recovered | FEVER 37.5 - 38.9 CONVULSION/SEIZURE |
| V952104 | 2 | Months | Male | Recovered | STERILE ABCESS/NODULE/NECROSIS SEVERE PAIN AND/OR SWELLING |
| V952107 | 5 | Years | Female | Recovered | FEVER 39.0 - 40.4 PNEUMONIA APATHY |
| V952109 | 5 | Years | Male | Recovered | FEVER 37.5 - 38.9 ARTHRALGIA/ARTHRITIS SEVERE PAIN AND/OR SWELLING |
| V952110 | 6 | Years | Female | Recovering | INJECTION SITE REACTION ABDOMINAL PAIN HEADACHE LETHARGY SEVERE PAIN AND/OR SWELLING ALLERGIC REACTION |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V952120 | 4 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V952124 | 4 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V952126 | 3 | Months | Male | Recovered | CONVULSION/SEIZURE |
| V952127 | 5 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V952128 | 4 | Years | Female | Recovered | FEVER 37.5 - 38.9 SEVERE PAIN AND/OR SWELLING |
| V952134 | 5 | Years | Female | Recovered | FEVER 37.5 - 38.9 SEVERE PAIN AND/OR SWELLING |
| V952143 | 5 | Years | Female | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA INJECTION SITE REACTION |
| V952152 | 4 | Years | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V952158 | 3 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING |
| V952159 | 2 | Months | Female | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING |
| V952160 | 5 | Months | Male | Recovered | FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE |
| V952175 | 2 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING FEVER - TEMPERATURE NOT RECORDED HYPOTONIC-HYPORESPONSIVE EPISODE FEVER - TEMPERATURE NOT RECORDED SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING |
| V952186 | 2 | Months | Male | Recovered | FEVER 39.0 - 40.4 |
| V952187 | 4 | Months | Male | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING |
| V952195 | 9 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE CONVULSION/SEIZURE |
| V952196 | 3 | Months | Female | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING |
| V952198 | 4 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE CONVULSION/SEIZURE |
| V952216 | 2 | Months | Female | Recovered | FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE SCREAMING EPISODE/PERSISTENT CRYING |
| V952219 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE SCREAMING EPISODE/PERSISTENT CRYING |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V952232 | 19 | Months | Female | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA TACHYCARDIA DYSPNOEA |
| V952238 | 5 | Months | Male | Recovered | FEVER 37.5 - 38.9 |

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| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V952243 | 6 | Months | Male | Recovered | IRRITABILITY INSOMNIA BULGING FONTONELLE LETHARGY VOMITING SEVERE PAIN AND/OR SWELLING FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING HYPOTONIC-HYPORESPONSIVE EPISODE FEVER - TEMPERATURE NOT RECORDED FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA FEVER - TEMPERATURE NOT RECORDED INJECTION SITE REACTION CHEST PAIN LETHARGY FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING FEVER - TEMPERATURE NOT RECORDED INJECTION SITE REACTION FEVER 37.5 - 38.9 |
| V952244 | 4 | Months | Female | Recovered | |
| V952245 | 16 | Months | Male | Recovered | |
| V952256 | 4 | Months | Male | Recovered | |
| V952257 | 18 | Months | Male | Recovered | |
| V952266 | 2 | Years | Male | Recovered | |
| V952270 | 4 | Months | Male | Recovered | |
| V952273 | 2 | Months | Female | Recovered | |
| V952281 | 18 | Months | Female | Recovered | |
| V952295 | 6 | Months | Female | Recovered | |
| V952306 | 19 | Months | Male | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V952306 | 19 | Months | Male | Recovered | FEVER ATAXIA ASTHENIA ANAEMIA ANOREXIA LETHARGY PAIN ARM CHILLS |
| V952312 | 5 | Months | Female | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING |
| V952313 | 5 | Months | Female | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING |
| V952314 | 5 | Months | Female | Recovered | FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE FEVER - TEMPERATURE NOT RECORDED SCREAMING EPISODE/PERSISTENT CRYING FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE FEVER 37.5 - 38.9 SEVERE PAIN AND/OR SWELLING INJECTION SITE REACTION |
| V952317 | 2 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE FEVER 37.5 - 38.9 SEVERE PAIN AND/OR SWELLING INJECTION SITE REACTION |
| V952320 | 5 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING FEVER 37.5 - 38.9 SEVERE PAIN AND/OR SWELLING FEVER 37.5 - 38.9 SEVERE PAIN AND/OR SWELLING FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING |
| V952341 | 4 | Months | Male | Recovered | |
| V952345 | 7 | Months | Male | Recovered | |
| V952346 | 18 | Months | Female | Recovered | |
| V952357 | 6 | Months | Male | Recovered | |
| V952387 | 2 | Months | Female | Recovered | |
| V952388 | 23 | Months | Male | Recovered | |
| V952406 | 5 | Months | Female | Recovered | |
| V952408 | 4 | Months | Male | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|-------|--------|-----------|---|
| V952420 | 5 | Years | Male | Recovered | FEVER INJECTION SITE REACTION |
| V952424 | 6 | Years | Female | Recovered | PALLOR NAUSEA INJECTION SITE PAIN |

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| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V952442 | 6 | Years | Male | Recovered | TREMOR |
| V952460 | 4 | Years | Male | Recovered | VASO-VAGAL REACTION INJECTION SITE REACTION FEVER 37.5 - 38.9 |
| V952478 | 5 | Years | Male | Recovered | SEVERE VOMITING AND/OR DIARRHEA FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA |
| V952484 | 4 | Years | Male | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA SEVERE PAIN AND/OR SWELLING |
| V952485 | 4 | Years | Male | Recovered | FEVER 37.5 - 38.9 |
| V952501 | 5 | Years | Female | Recovered | ARTHRALGIA/ARTHRITIS SEVERE PAIN AND/OR SWELLING ALLERGIC REACTION |
| V952504 | 5 | Years | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED CELLULITIS SEVERE PAIN AND/OR SWELLING SEVERE PAIN AND/OR SWELLING |
| V952509 | 4 | Years | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V952574 | 7 | Months | Female | Recovered | SEVERE VOMITING AND/OR DIARRHEA IRRITABILITY VOMITING |
| V952577 | 4 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED ALLERGIC REACTION |
| V952578 | 4 | Months | Female | Recovered | RASHES |
| V952579 | 5 | Years | Male | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V952581 | 6 | Months | Male | Recovered | FEVER 39.0 - 40.4 SEVERE VOMITING AND/OR DIARRHEA |
| V952582 | 8 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V952583 | 8 | Months | Female | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING HYPOTONIC-HYPORESPONSIVE EPISODE INFECTIVE ABCESS |
| V952603 | 4 | Months | Female | Recovered | CONVULSION/SEIZURE |
| V952604 | 19 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V952605 | 2 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V952632 | 2 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE SEVERE VOMITING AND/OR DIARRHEA FEVER 39.0 - 40.4 |
| V952645 | 19 | Months | Male | Recovered | |
| V952646 | 4 | Years | Female | Recovered | FEVER 37.5 - 38.9 FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING FEVER - TEMPERATURE NOT RECORDED HYPOTONIC-HYPORESPONSIVE EPISODE CONVULSION/SEIZURE |
| V952647 | 5 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V952650 | 5 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED HYPOTONIC-HYPORESPONSIVE EPISODE CONVULSION/SEIZURE |
| V952652 | 4 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING FEVER IRRITABILITY RASH |
| V952661 | 3 | Months | Male | Recovered | FEVER 39.0 - 40.4 |
| V952663 | 4 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE SEVERE PAIN AND/OR SWELLING FEVER 37.5 - 38.9 CONVULSION/SEIZURE |
| V952667 | 7 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V952672 | 4 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V952675 | 2 | Months | Male | Recovered | CONVULSION/SEIZURE |
| V952676 | 18 | Months | Male | Recovered | FEVER 37.5 - 38.9 CONVULSION/SEIZURE |
| V952678 | 2 | Months | Male | Recovered | FEVER 37.5 - 38.9 CONVULSION/SEIZURE |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V952737 | 5 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V952739 | 4 | Years | Female | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA FEVER 37.5 - 38.9 |
| V952795 | 5 | Months | Female | Recovered | ALLERGIC REACTION |
| V952798 | 17 | Months | Male | Recovered | |
| V952799 | 5 | Months | Male | Recovered | FEVER 37.5 - 38.9 |

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V952802 | 3 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V958114 | 4 | Years | Female | - | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V958162 | 5 | Years | Female | - | SEVERE PAIN AND/OR SWELLING |
| V958185 | 2 | Months | Female | - | SEVERE PAIN AND/OR SWELLING |
| V958187 | 3 | Months | Male | - | SEVERE PAIN AND/OR SWELLING |
| V958193 | 4 | Years | Male | - | FEVER 37.5 - 38.9 |
| V958203 | 4 | Months | Male | - | SCREAMING EPISODE/PERSISTENT CRYING |
| V958215 | 4 | Months | Male | - | FEVER 37.5 - 38.9 |
| V958221 | 5 | Years | Male | - | SEVERE PAIN AND/OR SWELLING |
| V958225 | 2 | Months | Male | - | CONVULSION/SEIZURE |
| V958226 | 2 | Years | Female | - | FEVER 39.0 - 40.4 |
| V958231 | 2 | Months | Male | - | RASHES |
| V958239 | 4 | Months | Male | - | SEVERE PAIN AND/OR SWELLING |
| | | | | | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | HYPOTONIC-HYPORESPONSIVE EPISODE |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| | | | | | SEVERE VOMITING AND/OR DIARRHEA |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| | | | | | FEVER 37.5 - 38.9 |
| | | | | | HYPOTONIC-HYPORESPONSIVE EPISODE |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| V958253 | 4 | Months | Female | - | |
| V958254 | 19 | Months | Male | - | |
| V9590192 | 18 | Months | Male | Recovered | |
| V9590378 | 4 | Years | Male | - | |
| V9590394 | 4 | Months | Male | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|-------------------------------------|
| V9590407 | 18 | Months | Male | Recovered | FEVER 39.0 - 40.4 |
| V9590459 | 5 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9590462 | 4 | Years | Female | Recovered | FEVER 37.5 - 38.9 |
| V9590463 | - | - | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V9590527 | 18 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9590528 | 9 | Months | Male | - | SCREAMING EPISODE/PERSISTENT CRYING |
| V9590579 | 4 | Months | Female | - | SEVERE PAIN AND/OR SWELLING |
| V9590728 | 5 | Years | Female | Recovered | FEVER 39.0 - 40.4 |
| V9590836 | 6 | Months | Female | Recovered | SEVERE VOMITING AND/OR DIARRHEA |
| V9590837 | 4 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V9590839 | 6 | Years | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V9590843 | 2 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9590886 | 4 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V9590891 | 5 | Years | Male | - | SEVERE PAIN AND/OR SWELLING |
| V9590912 | 5 | Years | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | ALLERGIC REACTION |
| | | | | | ALLERGIC REACTION |
| | | | | | SEVERE PAIN AND/OR SWELLING |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|----------------------------------|
| V9590991 | 4 | Years | Male | Recovered | FEVER 39.0 - 40.4 |
| V9591077 | 6 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9591078 | 18 | Months | Female | - | FEVER - TEMPERATURE NOT RECORDED |
| V9591210 | 4 | Years | Female | - | SEVERE PAIN AND/OR SWELLING |
| | | | | | FEVER |
| | | | | | INJECTION SITE REACTION |
| | | | | | SEVERE PAIN AND/OR SWELLING |

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|----------|----|--------|--------|------------|--|
| V9591317 | - | - | - | Recovering | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9591373 | 4 | Years | Male | Recovered | FEVER 37.5 - 38.9 CRYING ABNORMAL IRRITABILITY RESTLESSNESS DELIRIUM |
| V9591374 | 6 | Years | Female | Recovering | SEVERE PAIN AND/OR SWELLING |
| V9591375 | 4 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9591378 | 18 | Months | Male | Recovered | ALLERGIC REACTION-SKIN |
| V9591461 | 4 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9591462 | 4 | Years | Male | Recovered | FEVER 37.5 - 38.9 SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9591473 | 4 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9591549 | 4 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9591571 | 18 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9591629 | 4 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE SCREAMING EPISODE/PERSISTENT CRYING |
| V9591655 | 4 | Years | Male | - | FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING |
| V9591656 | 18 | Months | Male | Recovering | SCREAMING EPISODE/PERSISTENT CRYING IRRITABILITY |
| V9591862 | 4 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING-PAST JOINTS SEVERE PAIN AND/OR SWELLING ALLERGIC REACTION-SKIN |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V9591864 | 8 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED HYPOTONIC-HYPORESPONSIVE EPISODE SEVERE VOMITING AND/OR DIARRHEA FEVER 37.5 - 38.9 SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9591908 | 5 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING-PAST JOINTS |
| V9591944 | 6 | Months | Male | Recovered | ALLERGIC REACTION-SKIN |
| V9591977 | 18 | Months | Male | - | INJECTION SITE REACTION |
| V9591978 | 0 | Months | Male | - | RASH |
| V9591981 | 18 | Months | Female | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING SEVERE PAIN AND/OR SWELLING |
| V9600178 | 2 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING SEVERE PAIN AND/OR SWELLING |
| V9600179 | 2 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE SCREAMING EPISODE/PERSISTENT CRYING |
| V9600180 | 2 | Years | Female | Recovered | ALLERGIC REACTION-SKIN |
| V9600181 | 5 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE SCREAMING EPISODE/PERSISTENT CRYING |
| V9600182 | 4 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V9600183 | 5 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V9600184 | 2 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED SEVERE VOMITING AND/OR DIARRHEA |
| V9600185 | 2 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V9600186 | 6 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V9600222 | 8 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING |
| V9600235 | 19 | Months | Male | Recovered | FEVER 39.0 - 40.4 |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|------|-----------|--|
| V9600263 | 6 | Months | Male | Recovered | INJECTION SITE REACTION IRRITABILITY BRADYAPNOEA |
| V9600264 | 18 | Months | Male | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |

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| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V9600274 | 6 | Years | Male | Recovered | CEDEMA |
| V9600356 | 2 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V9600357 | 4 | Months | Female | Recovered | INFECTIVE ABCESS |
| V9600358 | 8 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V9600359 | 3 | Months | Male | Recovered | SEVERE VOMITING AND/OR DIARRHEA |
| V9600361 | 2 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V9600496 | 10 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V9600497 | 7 | Months | Female | Recovered | ALLERGIC REACTION-SKIN |
| V9600498 | 5 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V9600504 | 2 | Months | Male | Recovered | CONVULSION/SEIZURE-FEBRILE |
| V9600513 | 5 | Years | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V9600533 | 6 | Years | Male | Recovered | FEVER 37.5 - 38.9 |
| V9600533 | 6 | Years | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V9600684 | 6 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING- 4 DAYS OR M |
| V9600760 | 6 | Months | Male | Recovered | RASHES-LOCAL |
| V9600761 | 5 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V960078 | 2 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V9600929 | 4 | Years | Female | Recovered | FEVER 37.5 - 38.9 |
| V9600943 | 2 | Months | Female | Recovered | SEVERE VOMITING AND/OR DIARRHEA |
| V9600944 | 5 | Months | Female | Recovered | SOMNOLENCE |
| V9600947 | 2 | Months | Male | Recovered | NAUSEA |
| V9600948 | 4 | Months | Female | Recovered | MALALISE |
| V9600983 | 6 | Months | Female | Recovered | CHILLS |
| V9600984 | 8 | Months | Male | Recovered | ALLERGIC REACTION-RESPIRATORY |
| V9600985 | 3 | Months | Female | Recovered | ALLERGIC REACTION-RESPIRATORY |
| V9601002 | 8 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V9601034 | 5 | Years | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V960107 | 4 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V9601133 | 2 | Months | Female | Recovered | SEVERE VOMITING AND/OR DIARRHEA |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | SEVERE PAIN AND/OR SWELLING |
| | | | | | FEVER 37.5 - 38.9 |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| | | | | | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| | | | | | CONVULSION/SEIZURE-FEBRILE |
| | | | | | FEVER 37.5 - 38.9 |
| | | | | | STERILE ABCESS/NODULE/NECROSIS |
| | | | | | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| | | | | | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | IRRITABILITY |
| | | | | | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| | | | | | FEVER 37.5 - 38.9 |
| | | | | | RASHES |
| | | | | | FEVER 37.5 - 38.9 |
| | | | | | SCREAMING EPISODE/PERSISTENT CRYING |
| | | | | | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V9601152 | 6 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V9601192 | 5 | Years | Female | Recovered | FEVER 37.5 - 38.9 |
| V9601222 | 4 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING-PAST JOINTS |
| | | | | | INJECTION SITE REACTION |

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|----------|----|--------|--------|-----------|--|
| V960127 | 4 | Years | Female | Recovered | FEVER 37.5 - 38.9 |
| V9601905 | 7 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING INJECTION SITE REACTION |
| V9601951 | 22 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING |
| V9602015 | 22 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9602270 | 5 | Years | Male | Recovered | FAINTNESS |
| V9602634 | 5 | Months | Male | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING SEVERE PAIN AND/OR SWELLING-PAST JOINTS FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING- 4 DAYS OR M ALLERGIC REACTION-RESPIRATORY & SKIN HYPOTONIC-HYPORESPONSIVE EPISODE SEVERE VOMITING AND/OR DIARRHEA DROWSINESS TREMOR FAINTNESS ABDOMINAL PAIN REDUCED CONSCIOUSNESS SCREAMING EPISODE/PERSISTENT CRYING ALLERGIC REACTION-SKIN |
| V9602738 | 4 | Years | Male | Recovered | |
| V9602798 | 4 | Months | Female | Recovered | |
| V9602804 | 5 | Years | Male | Recovered | |
| V9602834 | 6 | Months | Female | Recovered | |
| V9602884 | 4 | Months | Male | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|------------|---|
| V9602946 | 18 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE SEVERE VOMITING AND/OR DIARRHEA SEVERE PAIN AND/OR SWELLING ALLERGIC REACTION RASHES |
| V9680160 | 5 | Years | Female | - | HYPOTONIC-HYPORESPONSIVE EPISODE SCREAMING EPISODE/PERSISTENT CRYING FEVER 37.5 - 38.9 |
| V9680766 | 5 | Years | - | - | SCREAMING EPISODE/PERSISTENT CRYING FEVER 37.5 - 38.9 |
| V9680828 | 4 | Years | Female | Recovering | SCREAMING EPISODE/PERSISTENT CRYING INJECTION SITE REACTION |
| V9680833 | 5 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING INJECTION SITE INFLAMMATION FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA INJECTION SITE REACTION OEDEMA SEVERE PAIN AND/OR SWELLING ALLERGIC REACTION |
| V9681185 | - | - | Female | - | HYPOTONIC-HYPORESPONSIVE EPISODE INJECTION SITE REACTION SCREAMING |
| V9681186 | 5 | Months | Male | - | FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING INJECTION SITE REACTION FEVER |
| V9690014 | 4 | Years | Female | - | FEVER - TEMPERATURE NOT RECORDED INJECTION SITE REACTION ALLERGIC REACTION-RESP |
| V9690015 | 5 | Years | Female | - | FEVER - TEMPERATURE NOT RECORDED INJECTION SITE INFLAMMATION |
| V9690019 | 19 | Months | Female | - | |
| V9690055 | 4 | Years | Female | Recovered | |
| V9690056 | 6 | Months | Female | Recovered | |
| V9690070 | 4 | Years | Male | - | |
| V9690083 | 4 | Years | Male | Recovered | |
| V9690084 | 5 | Years | Female | Recovered | |
| V9690087 | 5 | Years | Female | - | |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|------|------------|--|
| V9690089 | 3 | Years | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING OEDEMA FEVER |
| V9690090 | 4 | Months | Male | Recovering | FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE |

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V9690092 | 5 | Months | Male | Recovered | FEVER |
| V9690094 | 4 | Years | Female | Recovered | INJECTION SITE INFLAMMATION INJECTION SITE REACTION FASHERS |
| V9690095 | 2 | Months | Male | Recovered | <u>CONVULSION/SEIZURE</u> |
| V9690099 | 5 | Months | Male | - | <u>HYPOTONIC-HYPORESPONSIVE EPISODE</u> |
| V9690100 | 2 | Months | Female | Recovered | IRRITABILITY |
| V9690102 | 18 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING-PAST JOINTS SEVERE PAIN AND/OR SWELLING SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO INFECTIVE ABCESS SEVERE PAIN AND/OR SWELLING FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING ALLERGIC REACTION-SKIN FASHERS |
| V9690103 | 4 | Years | Female | Recovered | FEVER 37.5 - 38.9 |
| V9690104 | 2 | Months | Male | Recovered | <u>CONVULSION/SEIZURE</u> |
| V9690106 | 6 | Months | Male | - | SCREAMING EPISODE/PERSISTENT CRYING ALLERGIC REACTION-SKIN FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE SCREAMING EPISODE/PERSISTENT CRYING <u>CONVULSION/SEIZURE</u> |
| V9690112 | 6 | Years | Male | Recovered | |
| V9690113 | - | - | Female | Recovered | |
| V9690115 | 6 | Months | Female | Recovered | |
| V9690116 | 4 | Months | Female | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V9690117 | 2 | Months | Male | - | FEVER - TEMPERATURE NOT RECORDED SCREAMING EPISODE/PERSISTENT CRYING IRRITABILITY |
| V9690118 | 2 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING INJECTION SITE REACTION MALAISE FEVER ALLERGIC REACTION-RESPIRATORY & SKIN SEVERE PAIN AND/OR SWELLING FEVER 37.5 - 38.9 STERILE ABCESS/NODULE/NECROSIS SEVERE PAIN AND/OR SWELLING FEVER - TEMPERATURE NOT RECORDED IRRITABILITY SEVERE PAIN AND/OR SWELLING SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO SCREAMING EPISODE/PERSISTENT CRYING IRRITABILITY SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO FEVER - TEMPERATURE NOT RECORDED SOMNOLENCE PALLOR LISTLESS SHAKING STIFFNESS BODY FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE SCREAMING EPISODE/PERSISTENT CRYING PALLOR CEDEMA CYANOSIS HYPOTONIA |
| V9690119 | 4 | Years | Male | - | |
| V9690120 | 5 | Years | Male | Recovered | |
| V9690124 | 5 | Years | Female | Recovered | |
| V9690126 | 5 | Years | Female | Recovered | |
| V9690137 | - | - | Male | Recovered | |
| V9690142 | 4 | Years | Female | Recovered | |
| V9690157 | 4 | Months | Male | - | |
| V9690159 | 2 | Months | Female | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|------|-----------|---|
| V9690164 | 5 | Months | Male | Recovered | FEVER 39.0 - 40.4 SCREAMING EPISODE/PERSISTENT CRYING IRRITABILITY Twitching |
| V9690174 | 5 | Years | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED INJECTION SITE REACTION |

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|----------|----|--------|--------|-----------|--|
| V9690184 | 4 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9690186 | - | - | Male | Recovered | SEVERE VOMITING AND/OR DIARRHEA |
| V9690186 | - | - | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9690188 | 17 | Months | Male | - | FEVER - TEMPERATURE NOT RECORDED INJECTION SITE REACTION OEDEMA HYPERTONIA FEELING HOT ARTHRITIS GLOSSY EYES FEVER 37.5 - 38.9 SOMNOLENCE OEDEMA SEVERE PAIN AND/OR SWELLING MALAISE PALLOR CYANOSIS BREATH HOLDING OEDEMA CYANOSIS ALLERGIC REACTION <u>CONVULSION/SEIZURE</u> INJECTION SITE INFLAMMATION |
| V9690190 | 5 | Years | Male | 0 | |
| V9690196 | 2 | Months | Male | Recovered | |
| V9690216 | 18 | Months | Male | Recovered | |
| V9690229 | 5 | Years | Female | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|------------|--|
| V9690231 | 7 | Months | Male | Recovered | FEVER 39.0 - 40.4 OEDEMA INSOMNIA CRYING ABNORMAL FEVER 39.0 - 40.4 INJECTION SITE INFLAMMATION SCREAMING EPISODE/PERSISTENT CRYING INJECTION SITE INFLAMMATION VOMITING SCREAMING EPISODE/PERSISTENT CRYING HYPOTONIC-HYPORESPONSIVE EPISODE SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO FEVER - TEMPERATURE NOT RECORDED SCREAMING EPISODE/PERSISTENT CRYING INJECTION SITE INFLAMMATION INJECTION SITE INFLAMMATION SOMNOLENCE HEADACHE HYPOTONIC-HYPORESPONSIVE EPISODE SEVERE VOMITING AND/OR DIARRHEA SOMNOLENCE FEVER SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9690233 | 2 | Years | Male | Recovered | |
| V9690235 | 3 | Months | Female | - | |
| V9690236 | 18 | Months | Male | - | |
| V9690238 | 2 | Months | Female | Recovered | |
| V9690244 | 5 | Months | Female | Recovered | |
| V9690245 | 4 | Years | Male | Recovered | |
| V9690246 | 2 | Months | Male | Recovered | |
| V9690248 | 5 | Months | Male | Recovered | |
| V9690249 | 4 | Years | Male | Recovered | |
| V9690250 | 6 | Months | Male | Recovering | |
| V9690270 | 4 | Years | Female | Recovered | |
| V9690271 | 18 | Months | Female | - | FEVER 37.5 - 38.9 OEDEMA <u>CONVULSION/SEIZURE</u> FEVER - TEMPERATURE NOT RECORDED HYPOTONIC-HYPORESPONSIVE EPISODE |
| V9690276 | 2 | Months | Male | Recovered | |
| V9690279 | 19 | Months | Female | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V9690298 | 17 | Months | Female | Recovered | FEVER 37.5 - 38.9 SOMNOLENCE MALAISE ANOREXIA INJECTION SITE PAIN INJECTION SITE INFLAMMATION |
| V9690310 | 40 | Years | Male | - | |

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| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|------------|--|
| V9690312 | 6 | Months | Male | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING CONVULSION/SEIZURE-FEBRILE |
| V9690323 | 5 | Months | Male | Recovering | SCREAMING EPISODE/PERSISTENT CRYING CONVULSION/SEIZURE |
| V9690324 | 2 | Months | Male | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING PALLOP SOMNOLENCE |
| V9690325 | 4 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE IPRITABILITY |
| V9690327 | 6 | Months | Female | Recovered | FEVER 37.5 - 38.9 SEVERE PAIN AND/OR SWELLING-PAST JOINTS |
| V9690329 | 9 | Months | Male | Recovered | FEVER 37.5 - 38.9 OEDEMA |
| V9690331 | 23 | Months | Female | Recovered | INJECTION SITE INFLAMMATION ANOREXIA |
| V9690333 | 3 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING OEDEMA RAPID EYE MOVEMENT |
| V9690335 | 2 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE SOMNOLENCE MALAISE |
| V9690336 | 4 | Months | Male | Recovered | FEVER 39.0 - 40.4 OEDEMA |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V9690338 | 22 | Months | Male | Recovered | FEVER 37.5 - 38.9 ANAPHYLAXIS SEVERE VOMITING AND/OR DIARRHEA SOMNOLENCE ALLERGIC REACTION-RESPIRATORY & SKIN |
| V9690344 | 2 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V9690345 | 6 | Years | Male | Recovered | INJECTION SITE INFLAMMATION |
| V9690347 | 20 | Months | Male | Recovered | FEVER 37.5 - 38.9 SOMNOLENCE |
| V9690349 | 5 | Years | Male | - | FEVER INJECTION SITE REACTION VOMITING ANOREXIA |
| V9690350 | 6 | Years | Male | Recovered | FEVER INJECTION SITE REACTION DIFFICULTY VOIDING |
| V9690353 | 3 | Months | Male | Recovered | FEVER 39.0 - 40.4 SCREAMING EPISODE/PERSISTENT CRYING |
| V9690354 | 3 | Months | Male | Recovered | VOMITING PALLOP DROWSINESS LETHARGY |
| V9690371 | 5 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9690373 | 5 | Years | Female | Recovered | FEVER 37.5 - 38.9 INJECTION SITE REACTION INJECTION SITE PAIN |
| V9690376 | 17 | Months | Female | - | ALLERGIC REACTION-SKIN |
| V9690378 | 2 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V9690393 | 4 | Months | Male | - | FEVER 39.0 - 40.4 IRRITABILITY ABNORMAL CRYING VOMITI |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V9690398 | 2 | Months | Male | Recovered | FEVER 39.0 - 40.4 |
| V9690400 | 4 | Months | Female | - | SCREAMING EPISODE/PERSISTENT CRYING OEDEMA |
| V9690401 | 4 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9690405 | 4 | Months | Male | - | FEVER 39.0 - 40.4 SEVERE PAIN AND/OR SWELLING |

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| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V9690408 | - | - | Male | Recovered | INJECTION SITE INFLAMMATION |
| V9690411 | 5 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING ALLERGIC REACTION |
| V9690418 | 5 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9690419 | 4 | Months | Female | Recovered | FEVER 39.0 - 40.4 |
| V9690429 | 2 | Months | Female | Recovered | FEVER 39.0 - 40.4 SCREAMING EPISODE/PERSISTENT CRYING OEDEMA |
| V9690455 | 4 | Years | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED INJECTION SITE REACTION RASHES |
| V9690457 | 4 | Years | Female | Recovered | FEVER 37.5 - 38.9 INJECTION SITE REACTION |
| V9690460 | 4 | Years | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED SEVERE VOMITING AND/OR DIARRHEA |
| V9690461 | 19 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO FEVER 39.0 - 40.4 SCREAMING EPISODE/PERSISTENT CRYING SOMNOLENCE ALLERGIC REACTION RASHES |
| V9690462 | 3 | Months | Male | - | <u>CONVULSION/SEIZURE</u> |
| V9690481 | 2 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE |
| V9690485 | 4 | Months | - | Recovered | FEVER SCREAMING |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V9690486 | 5 | Years | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED SCREAMING EPISODE/PERSISTENT CRYING MYALGIA MALAISE PAIN |
| V9690499 | 2 | Years | Female | - | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING INJECTION SITE INFLAMMATION IRRITABILITY |
| V9690507 | 4 | Years | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING |
| V9690507 | 4 | Years | Male | Recovered | ALLERGIC REACTION-SKIN |
| V9690510 | 22 | Months | Female | - | HYPOTONIC-HYPORESPONSIVE EPISODE SOMNOLENCE VOMITING INJECTION SITE PAIN |
| V9690511 | 5 | Years | Male | Recovered | FEVER 37.5 - 38.9 INJECTION SITE INFLAMMATION MALAISE ABDOMINAL PAIN |
| V9690514 | 4 | Years | Male | Recovered | INJECTION SITE INFLAMMATION ALLERGIC REACTION |
| V9690531 | 4 | Years | Male | - | CELLULITIS SEVERE PAIN AND/OR SWELLING |
| V9690537 | 4 | Months | Male | - | HYPOTONIC-HYPORESPONSIVE EPISODE INJECTION SITE REACTION |
| V9690539 | - | - | Male | Recovered | INJECTION SITE INFLAMMATION |
| V9690551 | 2 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V9690553 | 6 | Months | Male | Recovered | SEVERE VOMITING AND/OR DIARRHEA INJECTION SITE INFLAMMATION IRRITABILITY DEHYDRATION CONVULSIONS |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V9690603 | 2 | Months | Male | Recovered | FEVER 37.5 - 38.9 SOMNOLENCE |
| V9690605 | 3 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED INJECTION SITE REACTION |
| V9690618 | 5 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9690646 | 2 | Years | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V9690648 | 3 | Months | Male | Recovered | SEVERE VOMITING AND/OR DIARRHEA INJECTION SITE REACTION FEVER - TEMPERATURE NOT RECORDED SCREAMING EPISODE/PERSISTENT CRYING SOMNOLENCE |
| V9690651 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 INJECTION SITE REACTION |
| V9690670 | 20 | Months | Female | Recovered | FEVER 39.0 - 40.4 SEVERE PAIN AND/OR SWELLING ALLERGIC REACTION-SKIN INJECTION SITE INFLAMMATION RASHES-LOCAL IRRITABILITY |
| V9690673 | 18 | Months | Female | Recovered | |
| V9690674 | 6 | Months | Male | Recovered | |
| V9690723 | 6 | Years | Female | Recovered | <u>CONVULSION/SEIZURE</u> FEVER - TEMPERATURE NOT RECORDED MALAISE SOMNOLENCE SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE FEVER INJECTION SITE REACTION FEVER 37.5 - 38.9 HYPOTONIC-HYPORESPONSIVE EPISODE |
| V9690742 | 4 | Years | Female | Recovered | |
| V9690746 | 5 | Years | Female | Recovered | |
| V9690795 | 6 | Months | Female | Recovered | |
| V9690867 | 2 | Months | Female | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V9690868 | 4 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED HYPOTONIC-HYPORESPONSIVE EPISODE SEVERE VOMITING AND/OR DIARRHEA INJECTION SITE REACTION SCREAMING EPISODE/PERSISTENT CRYING FEVER - TEMPERATURE NOT RECORDED <u>CONVULSIONS</u> IRRITABILITY ANAEMIA SEVERE PAIN AND/OR SWELLING-PAST JOINTS PALLOR HYPOTONIA VOMITING IRRITABILITY |
| V9690876 | 19 | Months | Female | Recovered | |
| V9690880 | 4 | Months | Male | Recovered | |
| V9690881 | 17 | Months | Male | Recovered | |
| V9690882 | 4 | Months | Male | Recovered | |
| V9690884 | 2 | Months | Female | Recovered | |
| V9690893 | 6 | Years | Male | Recovered | ALLERGIC REACTION-RESPIRATORY & SKIN INJECTION SITE INFLAMMATION PALLOR DELIRIUM |
| V9690894 | 6 | Years | Male | Recovered | INJECTION SITE INFLAMMATION FEVER SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO FEVER 37.5 - 38.9 SOMNOLENCE SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO FEVER - TEMPERATURE NOT RECORDED HEADACHE MALAISE NAUSEA INJECTION SITE INFLAMMATION URTICARIA |
| V9690901 | 5 | Years | Female | Recovered | |
| V9690907 | 4 | Months | Female | Recovered | |
| V9690916 | 18 | Months | Female | Recovered | |
| V9690929 | 6 | Years | Female | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V9690944 | 5 | Years | Male | Recovered | INJECTION SITE INFLAMMATION |
| V9690955 | 2 | Months | Female | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE SCREAMING EPISODE/PERSISTENT CRYING |
| V9690959 | 2 | Months | Male | Recovered | FEVER 39.0 - 40.4 SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING |

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| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V9690961 | 5 | Months | Female | Recovered | INJECTION SITE REACTION FEVER 37.5 - 38.9 |
| V9690965 | 5 | Months | Male | Recovered | INJECTION SITE INFLAMMATION NERVOUSNESS FEVER 37.5 - 38.9 <u>CONVULSION/SEIZURE-FEBRILE</u> NERVOUSNESS |
| V9690968 | 18 | Months | Female | Recovered | FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING |
| V9690976 | 6 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE RIGORS |
| V9690984 | 6 | Months | Female | Recovered | APATHY SEVERE PAIN AND/OR SWELLING-4 DAYS OR |
| V9690992 | 4 | Years | Male | Recovered | FEVER 39.0 - 40.4 INJECTION SITE INFLAMMATION |
| V9691045 | 4 | Months | Male | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING |
| V9691051 | 4 | Months | Male | Recovered | FEVER 39.0 - 40.4 NERVOUSNESS SEVERE PAIN AND/OR SWELLING-4 DAYS OR |
| V9691052 | 2 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED SCREAMING EPISODE/PERSISTENT CRYING INJECTION SITE INFLAMMATION |
| V9691056 | 4 | Years | Female | Recovered | INJECTION SITE REACTION |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V9691062 | 6 | Months | Male | Recovered | NERVOUSNESS ALLERGIC REACTION-SKIN FACE OEDEMA INJECTION SITE REACTION FEVER 39.0 - 40.4 SEVERE VOMITING AND/OR DIARRHEA <u>CONVULSION/SEIZURE-FEBRILE</u> FEVER >= 40.5 |
| V9691099 | 2 | Years | Female | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING SOMNOLENCE INSOMNIA NERVOUSNESS |
| V9691141 | 6 | Months | Female | Recovered | INJECTION SITE REACTION FEVER - TEMPERATURE NOT RECORDED HEADACHE NERVOUSNESS SOMNOLENCE |
| V9691188 | 2 | Years | Male | Recovered | MALAISE FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA INJECTION SITE INFLAMMATION FEVER - TEMPERATURE NOT RECORDED |
| V9691193 | 5 | Years | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING-4 DAYS OR |
| V9691340 | 5 | Years | Male | Recovered | INFECTIVE ABCESS FEVER 39.0 - 40.4 SOMNOLENCE EPISTAXIS SEVERE PAIN AND/OR SWELLING-4 DAYS OR |
| V9691341 | 7 | Months | Female | Recovered | |
| V9691341 | 7 | Months | Female | Recovered | |
| V9691451 | 7 | Months | Male | Recovered | |
| V9691495 | 6 | Years | Male | Recovered | |
| V9691924 | 9 | Months | Female | Recovered | |
| V9691970 | 6 | Years | Male | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|---------|---|
| V9692008 | 22 | Months | Female | - | FEVER 37.5 - 38.9 ALLERGIC REACTION-SKIN |

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| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V9692052 | 2 | Months | Male | Recovered | HYPOKINESIA HEAT RASH FEVER - TEMPERATURE NOT RECORDED ALLERGIC REACTION-SKIN |
| V9692079 | 5 | Years | Female | Recovered | FEVER 39.0 - 40.4 SEVERE VOMITING AND/OR DIARRHEA HEADACHE ASTHMA INJECTION SITE REACTION HYPOTONIA ALLERGIC REACTION-RESPIRATORY & SKIN ANOREXIA |
| V9692086 | 19 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9692092 | 18 | Months | Female | Recovered | CRYING ABNORMAL |
| V9692095 | 19 | Months | Male | - | ALLERGIC REACTION-SKIN |
| V9692096 | 17 | Months | Female | Recovered | INJECTION SITE INFLAMMATION DYSPONOEA TEMPERATURE CHANGED SENSATION FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA TREMOR SOMNOLENCE |
| V9692105 | 6 | Years | Female | - | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO FEVER - TEMPERATURE NOT RECORDED SEVERE VOMITING AND/OR DIARRHEA |
| V9692106 | 18 | Months | Male | Recovered | |
| V9692123 | 20 | Months | Male | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V9692123 | 20 | Months | Male | Recovered | CRYING ABNORMAL CONVULSION/SEIZURE-FEBRILE INJECTION SITE INFLAMMATION |
| V9692131 | 19 | Months | Male | - | FEVER - TEMPERATURE NOT RECORDED HYPOKINESIA NERVOUSNESS SEVERE PAIN AND/OR SWELLING |
| V9692149 | - | - | Male | Recovered | INJECTION SITE INFLAMMATION |
| V9692151 | 22 | Months | Female | Recovered | INJECTION SITE INFLAMMATION |
| V9692157 | 18 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED NERVOUSNESS SEVERE PAIN AND/OR SWELLING-4 DAYS OR |
| V9692215 | 18 | Months | Female | Recovered | INJECTION SITE BRUISING ANOREXIA HYPOTONIC-HYPORESPONSIVE EPISODE FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA SOMNOLENCE |
| V9692225 | 20 | Months | Male | Recovered | FEVER 39.0 - 40.4 SEVERE VOMITING AND/OR DIARRHEA |
| V9692226 | 3 | Years | Male | Recovered | SEVERE VOMITING AND/OR DIARRHEA FEVER 39.0 - 40.4 SEVERE VOMITING AND/OR DIARRHEA NERVOUSNESS |
| V9692229 | 18 | Months | Female | Recovered | INJECTION SITE REACTION SEVERE PAIN AND/OR SWELLING-4 DAYS OR |
| V9692230 | 17 | Months | Female | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING SOMNOLENCE DELIRIUM |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|------|-----|---------|---------------|
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|----------|----|--------|--------|-----------|---|
| V9692242 | 17 | Months | Male | Recovered | FEVER 39.0 - 40.4 SEVERE VOMITING AND/OR DIARRHEA INJECTION SITE REACTION RASHES-LOCAL |
| V9700166 | 17 | Months | Male | Recovered | FEVER 37.5 - 38.9 INJECTION SITE REACTION |
| V9702864 | 5 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING-4 DAYS OR |
| V9703085 | 18 | Months | Female | Recovered | ARTHRALGIA/ARTHRITIS |
| V9790074 | 4 | Months | Female | Recovered | FEVER 39.0 - 40.4 |
| V9790088 | 5 | Years | Male | Recovered | FEVER 39.0 - 40.4 INJECTION SITE REACTION |
| V9790121 | 17 | Months | Female | Recovered | INJECTION SITE REACTION |
| V9790135 | 18 | Months | Male | Recovered | SEVERE PAIN AND/OR SWELLING-PAST JOINTS |
| V9790182 | 6 | Years | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED SOMNOLENCE NAUSEA SEVERE PAIN AND/OR SWELLING ALLERGIC REACTION-SKIN RHINITIS FACE OEDEMA INJECTION SITE INFLAMMATION |
| V9790287 | 5 | Years | Male | Recovered | INJECTION SITE REACTION FEVER NAUSEA FATIGUE NERVOUSNESS SEVERE PAIN AND/OR SWELLING-PAST JOINTS APATHY NAUSEA FATIGUE FEVER |
| V9790296 | 4 | Years | Female | - | |
| V9790351 | 5 | Years | Female | Recovered | |
| V9790352 | 5 | Years | Female | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V_Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V9790368 | 4 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9790370 | 7 | Months | Female | Recovered | FEVER 39.0 - 40.4 HYPOTONIC-HYPORESPONSIVE EPISODE |
| V9790423 | 6 | Months | Male | - | SEVERE VOMITING AND/OR DIARRHEA RHINITIS CRYING ABNORMAL APATHY SOMNOLENCE FEVER 37.5 - 38.9 TREMOR CRYING ABNORMAL SCREAMING EPISODE/PERSISTENT CRYING |
| V9790477 | 6 | Months | Male | Recovered | FEVER 39.0 - 40.4 OCULOGYRIC CRISIS TREMOR MALAISE FEVER 37.5 - 38.9 INJECTION SITE BRUISING INJECTION SITE INFLAMMATION INJECTION SITE INFLAMMATION EYE PAIN FEVER SCREAMING EPISODE/PERSISTENT CRYING ANOREXIA FEVER 39.0 - 40.4 INJECTION SITE REACTION FEVER - TEMPERATURE NOT RECORDED SCREAMING EPISODE/PERSISTENT CRYING INJECTION SITE REACTION |
| V9790510 | 2 | Months | Male | Recovered | |
| V9790511 | 3 | Months | Female | Recovered | |
| V9790513 | 5 | Months | Male | Recovered | |
| V9790532 | 5 | Years | Female | | |
| V9790590 | 4 | Years | Female | Recovered | |
| V9790632 | 4 | Years | Female | - | |
| V9790638 | 2 | Months | Female | Recovered | |
| V9790644 | 8 | Months | Male | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V_Number | Age | Unit | Sex | Outcome | Adverse event |
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|----------|----|--------|--------|-----------|--|
| V9790647 | 5 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING ANOREXIA VOMITING SOMNOLENCE |
| V9790650 | 4 | Months | Male | Recovered | FEVER 39.0 - 40.4 |
| V9790651 | 8 | Months | Female | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING |
| V9790678 | 2 | Months | Male | Recovered | FEVER 37.5 - 38.9 |
| V9790710 | 5 | Months | Female | Recovered | INJECTION SITE INFLAMMATION |
| V9790728 | 5 | Months | Female | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V9790732 | 5 | Months | Male | Recovered | HYPOTONIC-HYPORESPONSIVE EPISODE INJECTION SITE PAIN APNOEA |
| V9790745 | 5 | Years | Female | Recovered | FEVER 39.0 - 40.4 |
| V9790749 | 5 | Years | Male | Recovered | INJECTION SITE INFLAMMATION SEVERE PAIN AND/OR SWELLING-4 DAYS OR |
| V9790756 | 4 | Years | Female | - | INJECTION SITE INFLAMMATION |
| V9790800 | 5 | Years | Male | - | FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING-PAST JOINTS |
| V9790801 | 4 | Years | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED VOMITING |
| V9790936 | 4 | Years | Male | Recovered | INJECTION SITE PAIN SEVERE VOMITING AND/OR DIARRHEA INJECTION SITE INFLAMMATION PALLOR MYALGIA |
| V9800603 | 18 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED |
| V9800748 | 2 | Years | Male | Recovered | <u>CONVULSION/SEIZURE-FEBRILE</u> FEVER - TEMPERATURE NOT RECORDED |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|--|-----|--------|--------|-----------|--|
| ff | | | | | |
| V9800748 | 2 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9801481 | 22 | Months | Male | Recovered | INJECTION SITE REACTION ALLERGIC REACTION-SKIN |
| V9801727 | 19 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V9890370 | 4 | Years | Male | Recovered | <u>CONVULSION/SEIZURE-FEBRILE</u> FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING- >4DAYS & |
| PAST JOINT | | | | | |
| RASHES-LOCAL VOMITING CELLULITIS | | | | | |
| V9890389 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 |
| V9890390 | 14 | Months | Female | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9890440 | 4 | Years | Male | - | INJECTION SITE INFLAMMATION |
| V9890441 | 4 | Years | Female | - | FEVER 39.0 - 40.4 SCREAMING EPISODE/PERSISTENT CRYING SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9890445 | 5 | Years | Female | Recovered | FEVER 37.5 - 38.9 VOMITING INJECTION SITE INFLAMMATION DIZZINESS |
| V9890446 | 5 | Years | Male | Recovered | FEVER 37.5 - 38.9 |
| V9890448 | 4 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9890451 | 4 | Years | Female | - | INJECTION SITE INFLAMMATION FEVER 37.5 - 38.9 |
| V9890454 | 4 | Years | Female | Recovered | INJECTION SITE REACTION ALLERGIC REACTION-SKIN |
| V9890458 | 4 | Years | Male | 0 | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9890504 | 6 | Months | Male | - | RASHES-LOCAL FEVER 39.0 - 40.4 ANOREXIA INJECTION SITE REACTION |

Adverse events reported following use of vaccine batch # 24017-11

Age

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| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|---|
| V9890508 | 4 | Years | Female | Recovered | FEVER 39.0 - 40.4 SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO ALLERGIC REACTION-SKIN |
| V9890518 | 6 | Months | Male | Recovered | FEVER 39.0 - 40.4 NERVOUSNESS |
| V9890530 | 5 | Years | Male | Recovered | INJECTION SITE INFLAMMATION |
| V9890536 | 4 | Years | Female | - | FEVER INJECTION SITE INFLAMMATION |
| V9890541 | 4 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING |
| V9890553 | 8 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED RASHES-GENERALIZED |
| V9890555 | 5 | Months | Female | Recovered | FEVER 37.5 - 38.9 SCREAMING EPISODE/PERSISTENT CRYING SEVERE PAIN AND/OR SWELLING-PAST JOINTS |
| V9890691 | 14 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED CONVULSION/SEIZURE-FEBRILE |
| V9890717 | 2 | Months | Female | Recovered | SOMNOLENCE |
| V9890726 | 4 | Months | Female | Recovered | FEVER 39.0 - 40.4 IRRITABILITY INJECTION SITE REACTION |
| V9890727 | 2 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING |
| V9890730 | 4 | Years | Female | Recovered | FEVER 37.5 - 38.9 INJECTION SITE REACTION |
| V9890731 | 4 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9890734 | 4 | Years | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9890735 | 4 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED HYPOTONIC-HYPORESPONSIVE EPISODE INJECTION SITE REACTION |
| V9890755 | 4 | Months | Female | Recovered | FEVER 37.5 - 38.9 INJECTION SITE REACTION IRRITABILITY |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|------------|--|
| V9890773 | 12 | Months | Male | Recovered | SCREAMING EPISODE/PERSISTENT CRYING RASHES |
| V9890779 | 4 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9890783 | 2 | Months | Female | Recovered | FEVER 39.0 - 40.4 IRRITABILITY INJECTION SITE REACTION |
| V9890784 | 2 | Months | Male | Recovered | IRRITABILITY CRYING ABNORMAL |
| V9890788 | 5 | Years | Male | Recovered | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9890799 | 9 | Months | Female | Recovered | FEVER 39.0 - 40.4 CONVULSION/SEIZURE-FEBRILE |
| V9890806 | 4 | Months | Male | Recovered | CRYING ABNORMAL |
| V9890816 | 6 | Months | Female | Recovered | FEVER 39.0 - 40.4 SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING IRRITABILITY INJECTION SITE REACTION |
| V9890820 | 4 | Years | Female | Recovered | INJECTION SITE REACTION CRYING ABNORMAL ALLERGIC REACTION-RESP |
| V9890848 | 3 | Months | Female | Recovered | IRRITABILITY |
| V9890853 | 4 | Years | Male | Recovered | INJECTION SITE INFLAMMATION |
| V9890859 | 4 | Months | Female | Recovering | FEVER FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA SCREAMING EPISODE/PERSISTENT CRYING |
| V9890871 | 2 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED SOMNOLENCE WHEEZING ALLERGIC REACTION-RESPIRATORY & SKIN |
| V9890874 | 6 | Months | Male | Recovered | INJECTION SITE REACTION |
| V9890883 | 3 | Years | Female | Recovered | SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |

Adverse events reported following use of vaccine batch # 24017-11

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| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V9890896 | 17 | Months | Male | Recovered | INJECTION SITE REACTION CRYING ABNORMAL FEVER 37.5 - 38.9 LISTLESS FEVER SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO HYPOTONIC-HYPORESPONSIVE EPISODE FEVER 39.0 - 40.4 |
| V9890912 | 7 | Months | Female | Recovered | |
| V9890916 | 5 | Years | Female | Recovered | |
| V9890932 | 5 | Years | Male | Recovered | |
| V9890961 | 4 | Months | Male | Recovered | |
| V9890964 | 6 | Months | Male | Recovered | |
| V9890974 | 2 | Months | Female | Recovered | FEVER - TEMPERATURE NOT RECORDED HYPOTONIC-HYPORESPONSIVE EPISODE APNOEA INJECTION SITE REACTION IRRITABILITY COUGH SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO FEVER 37.5 - 38.9 IRRITABILITY FEVER 37.5 - 38.9 SEVERE VOMITING AND/OR DIARRHEA CRYING ABNORMAL INJECTION SITE REACTION ALLERGIC REACTION-SKIN FEVER - TEMPERATURE NOT RECORDED SOMNOLENCE MYALGIA FEVER - TEMPERATURE NOT RECORDED SOMNOLENCE HIVES ALLERGIC REACTION-RESP CELLULITIS SEVERE PAIN AND/OR SWELLING-4 DAYS OR MO |
| V9890990 | 4 | Years | Female | - | |
| V9891020 | 22 | Months | Male | Recovered | |
| V9891021 | 4 | Months | Male | Recovered | |
| V9891073 | 6 | Months | Female | Recovered | |
| V9891080 | 5 | Years | Female | 0 | |
| V9891547 | 18 | Months | Male | Recovered | |
| V9891677 | 19 | Months | Male | Recovered | |

Adverse events reported following use of vaccine batch # 24017-11

| V Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|-----------|--|
| V9891904 | 19 | Months | Male | Recovered | FEVER - TEMPERATURE NOT RECORDED CRYING ABNORMAL SOMNOLENCE LETHARGY SEVERE PAIN AND/OR SWELLING ALLERGIC REACTION-RESP ANOREXIA SOMNOLENCE ALLERGIC REACTION-RESP FEVER 39.0 - 40.4 IRRITABILITY INJECTION SITE REACTION CRYING ABNORMAL ASTHMA AGGRAVATED VOMITING NAUSEA |
| V9900290 | 4 | Months | Female | Recovered | |
| V9990140 | 6 | Months | Male | Recovered | |

Act - Hib
Exp. Apr. 1996

6 adverse events
Combined w/DPT-P @ PENTA.

* CAVEAT: The vast majority of reports on which this summary is based are submitted by health practitioners. Each report represents the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports to the Population and Public Health Branch has not been reviewed as to cause and effect relationship by Population and Public Health Branch scientists. Only a small proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse events. Reports submitted by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data will be used only for your personal use or within your immediate organization.

Please note the following:

1. When a case goes over the page, the V_number line may be repeated.
2. The first two digits of the V_number indicate the year the report was received at Health Canada.

Adverse events reported following use of vaccine batch # K0421

| V_Number | Age | Unit | Sex | Outcome | Adverse event |
|----------|-----|--------|--------|---------|-------------------------------------|
| V958185 | 2 | Months | Female | - | SEVERE PAIN AND/OR SWELLING |
| V958187 | 3 | Months | Male | - | SEVERE PAIN AND/OR SWELLING |
| V958203 | 4 | Months | Male | - | SCREAMING EPISODE/PERSISTENT CRYING |
| V958226 | 2 | Years | Female | - | FEVER 39.0 - 40.4 |
| | | | | | RASHES |
| V958231 | 2 | Months | Male | - | SEVERE PAIN AND/OR SWELLING |
| V958254 | 19 | Months | Male | - | FEVER - TEMPERATURE NOT RECORDED |
| | | | | | SEVERE PAIN AND/OR SWELLING |