

PEDIACEL®

Pertussis Vaccine-Acellular Combined with Diphtheria and Tetanus Toxoids (Adsorbed), Inactivated Poliovirus Vaccine (Vero cell) Types 1, 2 and 3 and *Haemophilus influenzae* Type b Polysaccharide Conjugated to Tetanus Protein.

DESCRIPTION

PEDIACEL® is a sterile, cloudy, uniform suspension for injection.

Each 0.5 mL dose contains:

- 20 µg pertussis toxoid
- 20 µg pertussis filamentous haemagglutinin
- 5 µg pertussis fimbriae 2 + 3
- 3 µg pertussis 69 kDa outer membrane protein
- ≥30 IU (15 LfU) diphtheria toxoid
- ≥40 IU (5 LfU) tetanus toxoid
- 10 µg *Haemophilus influenzae* type b polysaccharide covalently bound to 20 µg tetanus protein
- 40 DAgU poliovirus inactivated type 1, Vero (Mahoney)
- 8 DAgU poliovirus inactivated type 2, Vero (MEF1)
- 32 DAgU poliovirus inactivated type 3, Vero (Saukett)
- 1.5 mg aluminum phosphate
- 0.6% v/v phenoxyethanol
- ≤0.02% polysorbate 80
- ≤50 ng albumin bovine serum
- <0.03 µg polymyxin B sulfate
- <0.02 µg neomycin
- <0.2 µg streptomycin sulfate
- ≤0.02% formaldehyde
- ≤0.1% glutaraldehyde
- water for injections to 0.5 mL

This product does not contain thiomersal.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Diphtheria toxoid is a cell-free preparation of diphtheria toxin detoxified with formaldehyde.

Tetanus toxoid is prepared by detoxification of tetanus toxin with formaldehyde.

Inactivated Poliomyelitis Vaccine (Vero Cell Origin) is a sterile suspension of three strains of poliovirus. The viruses are grown in cultures of VERO cells, a continuous line of monkey kidney cells, by the microcarrier technique. The viruses are concentrated, purified, and made noninfectious by inactivation with formaldehyde. Purification procedures eliminate measurable amounts of neomycin, streptomycin and polymyxin B used in vaccine production, but traces may be present.

The Hib vaccine component, PRP-T (purified polyribose ribitol phosphate capsular polysaccharide of *Haemophilus influenzae* type b, covalently bound to tetanus protein), is the same active ingredient as in the currently registered Act-HIB®.

The 5 component pertussis antigens, pertussis toxoid (PT), filamentous haemagglutinin (FHA), 69kDa membrane protein (pertactin or PRN) and fimbriae 2 and 3 (FIM), contained

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in PEDIACEL[®] are the same as those in TRIPACEL[®], QUADRACEL[®], or POLIACEL[®]. TRIPACEL[®] consists of an acellular pertussis vaccine combined with diphtheria and tetanus toxoids (DTaP), and has lesser amounts of PT and FHA, while QUADRACEL[®] and POLIACEL[®] have pertussis formulations that are similar to PEDIACEL[®]. QUADRACEL contains DTaP combined with inactivated poliovirus vaccine (IPV). POLIACEL[®] consists of Act-HIB[®] reconstituted with QUADRACEL[®] resulting in a combination of vaccine antigens that are similar to the fully liquid PEDIACEL[®] at the time of administration.

PHARMACOLOGY

Clinical Trials

Studies of Protective efficacy of TRIPACEL[®] against Pertussis

A randomised controlled double-blind efficacy study was conducted in Sweden (Trial 1) where 2,551 infants received the regular formulation of TRIPACEL[®] (containing lower concentrations of PT and FHA than PEDIACEL[®]) and 2,539 received a control vaccine containing diphtheria and tetanus toxoids at 2, 4 and 6 months of age. TRIPACEL[®] was shown to have an absolute vaccine efficacy of 85% (95% CI: 81%-89%) against pertussis disease (defined as at least 21 days of paroxysmal cough with culture, serologic, or epidemiologic confirmation of infection with *Bordetella pertussis*). The incidence of local and systemic reactions after administration of TRIPACEL[®] was comparable to the Diphtheria Tetanus Vaccine (DT) control group.

A second randomised, double-blind controlled efficacy trial (Trial 2) was carried out in Sweden with 82,892 infants comparing 3 acellular pertussis and one European whole-cell DPT vaccines where 20,746 infants received a “hybrid” formulation of TRIPACEL[®] (DTaP) which contained the same concentration of pertussis antigens as PEDIACEL[®], at 2, 4 and 6 (n = 2,552) or 3, 5 and 12 (n = 18,194) months of age. The “hybrid” TRIPACEL[®] and the European whole-cell DPT vaccine had similar and high efficacy against culture-confirmed pertussis irrespective of duration. The other acellular pertussis combination vaccines were less effective. Rates of adverse events were less than or comparable to the rates observed in the other acellular pertussis and European whole-cell DPT groups in this study.

Immunogenicity of PEDIACEL[®]

In a clinical trial conducted in Canada, infants received either PEDIACEL[®] (n = 339), PENTA[®][Act-HIB[®] reconstituted with a whole-cell pertussis DTP-IPV vaccine] (n = 112), POLIACEL[®] [QUADRACEL[®] used to reconstitute Act-HIB[®]](n = 335), or QUADRACEL[®] and Act-HIB[®], given at separate sites at the same visit (n = 113) at 2, 4 and 6 months of age. Of the 899 children enrolled, 798 received a fourth dose of the same vaccine at 18-20 months of age. Serologic responses are shown in Table 1.

The following antibody levels are considered to be protective: diphtheria, diphtheria antitoxin levels ≥ 0.01 IU/mL; tetanus, tetanus antitoxin levels ≥ 0.01 IU/mL; poliomyelitis, neutralising poliovirus antibody titre levels $\geq 1:8$; and, invasive *Haemophilus influenzae* type b disease, anti-PRP antibody response ≥ 0.15 μ g/mL. Long-term protection against invasive *H. influenzae* type b disease is thought to correlate with an anti-PRP response of ≥ 1.0 μ g/mL.

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Table 1: Antibody responses observed one month after a third and fourth dose with PEDIACEL[®] or POLIACEL[®]

	1 month Post-Dose 3 (7 months of age)		1 month Post-Dose 4 (17 - 19 months of age)	
	PEDIACEL [®]	POLIACEL [®]	PEDIACEL [®]	POLIACEL [®]
Antibody Response	(n = 324)	(n = 322)	(n = 300)	(n = 296)
% anti-PRP:				
≥0.15 µg/mL	97.9	98.4	100	100
≥1.0 µg/mL	88.9	84.7	99.0	99.0
% polio ≥1:8:				
Type 1	100	99.4	100	100
Type 2	100	100	100	100
Type 3	100	99.4	100	100
GMT:				
PT	87	89	222	182
FHA	155	153	266	245
FIM	277	244	842	855
Pertactin	55.4	55.9	208	208
% diphtheria antitoxin				
≥0.01 IU/mL	100	98.4	100	100
% tetanus antitoxin				
≥0.01 EU/mL	100	100	100	100
<p>Note: GMT – Geometric Mean Titre PT – Pertussis Toxoid FHA – Filamentous Haemagglutinin FIM – Fimbriae 2 and 3</p>				

In clinical trials the anti-PRP responses have not been assessed after each dose of a three dose primary series with PEDIACEL[®]. The anti-PRP responses conferred by PEDIACEL[®] have not been studied in populations who have a peak incidence of invasive Hib disease at an earlier age, such as aboriginals. In the Canadian experience with universal childhood immunisation, POLIACEL[®] (a combination containing the same vaccine antigens as PEDIACEL[®]) has provided effective control of Hib disease.

The pertussis antibody responses observed with PEDIACEL[®] were comparable to those observed following administration of the two different formulations of TRIPACEL[®] (Component Pertussis Vaccine Combined with Diphtheria and Tetanus Toxoids Adsorbed), given at 2, 4 and 6 months, in the two Swedish pertussis efficacy trials (Table 2).

Table 2: Comparison of pertussis antibody GMTs obtained one month after a 3-dose primary series given at 2, 4 and 6 months of age with TRIPACEL® in the two Swedish efficacy trials with those reported in a Canadian trial with PEDIACEL®

		TRIPACEL® Sweden Trial 1	TRIPACEL® Sweden Trial 2	PEDIACEL® Canadian Trial
Antibody to:		(n = 178)	(n = 80)	(n = 320)
PT	GMT	49.43	51.64	86.7
	95% CI	44.8 - 54.4	44.8 - 59.5	80.8 - 93.0
FHA	GMT	34.12	57.02	155
	95% CI	30.8 - 37.8	49.1 - 66.2	147 - 164
Pertactin	GMT	116	134	55.4
	95% CI	103 - 132	111 - 163	48.8 - 62.8
FIM	GMT	351	352	277
	95% CI	301 - 408	273 - 454	243 - 317
<p>Note: *The TRIPACEL® used in Sweden Trial 2 was a “hybrid” formulation of the currently registered TRIPACEL® which had higher amounts of PT and FHA and contained pertussis antigen concentrations that were similar to those for PEDIACEL®.</p>				

INDICATIONS

PEDIACEL® is indicated for the primary immunisation of children from 2 months to 12 months against diphtheria, tetanus, whooping cough, poliomyelitis and invasive *Haemophilus influenzae* type b disease.

PEDIACEL® is also indicated for the fourth dose for children from 15 months of age up to 20 months who have been immunised previously with up to three doses of diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b disease vaccines.

CONTRAINDICATIONS

Allergy to any component of PEDIACEL®, (see components listed in DESCRIPTION) or an anaphylactic or other allergic reaction to a previous dose of DPT, TRIPACEL®, Act-HIB®, IPV, or a previous dose of this vaccine are contraindications to vaccination.

Encephalopathy not due to an identifiable cause, occurring within 7 days of a prior whole-cell or acellular DPT immunisation and characterised by a severe acute neurological illness with prolonged seizures and/or unconsciousness and/or focal neurological signs, (but not a simple febrile convulsion) is a contraindication to vaccination.

PRECAUTIONS

The following events require consideration of whether further doses of PEDIACEL® should be given:

- fever $\geq 40.5^{\circ}\text{C}$ within 48 hours of a dose of PEDIACEL®, not due to another identifiable cause;

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- hypotonic/hyporesponsive episodes within 48 hours. A hypotonic/hyporesponsive episode is one in which the child becomes pale, limp and unresponsive, lasting from 10 minutes to 36 hours. Shallow respiration and cyanosis are frequently observed. However, resuscitation is rarely required;
- persistent inconsolable screaming >3 hours, within 48 hours,
- convulsions, with or without fever, within 3 days.

Clinical data in such patients are inadequate. The Australian National Health and Medical Research Council recommends completion of the primary course of vaccination as in its view there is no evidence that these reactions increase the risk of neurological sequelae. PEDIACEL[®] should be deferred in children with a progressive, evolving, or unstable neurologic condition (including seizures) because administration of the pertussis component may coincide with the onset of overt manifestations of such disorders and result in confusion about causation. It is prudent to defer immunisation with pertussis vaccine until further observation and study have clarified the child's neurologic status. In addition, the effect of treatment, if any, can be assessed. Vaccination with PEDIACEL[®] may be deferred in children who have had a convulsion in the past three weeks. Immunisation with PEDIACEL[®] should be undertaken when the condition has been controlled or stabilised or resolved.

When immunisation with pertussis vaccine is contraindicated, immunisation against diphtheria, tetanus, poliomyelitis and invasive Hib disease, when necessary, may be continued with Adsorbed Diphtheria and Tetanus Vaccine, Inactivated Poliovirus Vaccine and/or *Haemophilus influenzae* Type b Polysaccharide Conjugated to Tetanus Protein Vaccine at separate sites and with separate syringes. The use of fractional doses in an attempt to reduce the severity of adverse reactions cannot be recommended because there is insufficient evidence on the safety or efficacy of such smaller doses.

When pertussis infections are occurring in the community the benefits of pertussis vaccine greatly outweigh any risk of vaccination.

Do not administer by intradermal or intravenous injection. Ensure that the needle does not enter a blood vessel.

As with other injectable vaccines, appropriate medical treatment and supervision should always be available in case of anaphylactic reactions. Adrenaline should always be readily available whenever the injection is given.

Intramuscular injections should be given with care in patients suffering from coagulation disorders because of the risk of haemorrhage.

Vaccination should be delayed in the presence of any acute disease.

Vaccination should be postponed in the event of febrile illness. The presence of a minor infection is not a contraindication.

PEDIACEL[®] should not be administered to children after their seventh birthday or to adults because of the quantity of diphtheria toxoid and pertussis antigens, may provoke enhanced local reactions, fever and malaise.

PEDIACEL[®] should not be administered into the buttocks due to the varying amount of fatty tissue in this region, nor by the intradermal route, since these methods of administration may induce a weaker immune response.

Use a separate sterile needle and syringe, or a sterile disposable unit, for each individual patient to prevent disease transmission.

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There are currently no data to support the use of PEDIACEL[®] in persons with an immunodeficiency. However, it is generally advised that HIV-infected individuals, both asymptomatic and symptomatic, should be immunised against diphtheria, pertussis tetanus, poliomyelitis and invasive Hib disease according to standard schedules.

Before administration of PEDIACEL[®], health-care providers should inform the patient, parent or guardian of the benefits and risks of immunisation, inquire about the recent health status of the patient and comply with any local requirements regarding information to be provided to the patient before immunisation and the importance of completing the immunisation series.

It is extremely important when a child returns for the next dose in the series that the patient, parent or guardian should be questioned concerning any symptoms and/or signs of an adverse reaction after the previous dose of vaccine.

Parents of infants and children with a personal or family history of convulsions should be informed of their children's increased risk of seizures following administration of any vaccine causing a febrile reaction. A family history of convulsions in parents and siblings is not a contraindication to pertussis vaccination. Paracetamol prophylaxis is particularly recommended for a child with a personal history of convulsions.

The vaccine must be given intramuscularly as subcutaneous administration increases the chances of a local reaction.

If PEDIACEL[®] is used in persons with malignancies, receiving immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, who are otherwise immunocompromised including HIV infected individuals or on corticosteroid therapy, the expected immune response may not be obtained.

As with any vaccine, immunisation with PEDIACEL[®] may not protect 100% of susceptible individuals.

The product must not be mixed with other vaccines in the same syringe.

Elective immunisation of persons over 6 months of age should be deferred during an outbreak of poliomyelitis because of the risk of provocation paralysis.

Physicians should be aware that recipients of *Haemophilus b* vaccine are not protected against Hib disease in the week after vaccination, prior to the onset of the protective effects of the vaccine.

The vaccine will not protect against non-typeable strains of *H. influenzae* which cause recurrent upper respiratory disease, otitis media and sinusitis.

Carcinogenicity, mutagenicity, impairment of fertility

PEDIACEL[®] has not been evaluated for carcinogenicity, mutagenicity or impairment of fertility.

Use in Pregnancy (Category B2)

Not relevant. PEDIACEL[®] should not be used in adults.

Use in Lactation

Not relevant. PEDIACEL[®] should not be used in adults.

Use in Elderly

PEDIACEL[®] should not be used in adults.

Use in Children

See DOSAGE AND ADMINISTRATION.

Interactions

PEDIACEL[®] should not be mixed with other vaccines or any other medicine prior to administration.

There are currently no data regarding the concomitant administration of PEDIACEL[®] with MMR or hepatitis B vaccine. The Australian Immunisation Handbook 2003 accepts that inactivated vaccines can be given during the same visit at separate sites with separate syringes. MMR and hepatitis B vaccine may be administered simultaneously with PEDIACEL[®] for children who are the recommended age to receive them.

Children receiving immunosuppressive therapy may have a reduced response to active immunisation procedures.

As with other intramuscular injections, PEDIACEL[®] should be given with caution to children on anticoagulant therapy.

Tetanus Immune Globulin or Diphtheria Antitoxin, if used, should be given at a separate site with a separate needle and syringe.

ADVERSE REACTIONS

In clinical trials done with PEDIACEL[®] and other acellular component pertussis vaccine combinations, recipients of component acellular pertussis combination vaccines had consistently lower rates of local and systemic reactions than those who received whole-cell DPT Polio Adsorbed, whether combined with Act-HIB[®] or given at separate sites.

The most frequent reactions include redness and tenderness at the injection site, irritability and slight fever. These symptoms usually occur within the first 24 hours after vaccination and may continue for 24 - 48 hours. There was a trend towards increasing local reaction rates at the booster doses, but these were still significantly lower than with whole-cell pertussis combination vaccines.

The rates of adverse events observed in children who received PEDIACEL[®] at 2, 4, 6 and 18 months of age during a clinical trial with the vaccine in Canada are shown in Table 3. One child enrolled in this study had afebrile seizures 24 hours after receiving the third dose of PEDIACEL[®].

Table 3: Adverse event rates (%) observed within 24 and 24 to 72 hours of vaccination with PEDIACEL® according to age and number of doses.

		1 st Dose		2 nd Dose		3 rd Dose		4 th Dose	
		2 months		4 months		6 months		18 months	
		(n = 336)		(n = 331)		(n = 330)		(n = 300)	
Reaction	Severity	0-24*	24-72*	0-24*	24-72*	0-24*	24-72*	0-24*	24-72*
Redness	severe [‡]	1.2	0	0.9	0.3	1.2	0.6	5.3	8.4
	any	6.8	0.6	12.7	3.6	9.7	3.1	19.7	18.8
Swelling	severe [‡]	5.1	0.6	3.6	0.9	3.3	1.8	4.0	5.4
	any	12.5	3.6	10.3	5.4	9.7	5.2	13.7	11.7
Tenderness	severe	0.6	0.3	2.4	0	1.8	0	1.7	1.0
	any	22.6	1.2	22.1	2.7	14.8	1.2	33.0	11.7
Fever	severe [§]	0	0	0	0	0	0	0	0.4
	any	13.4	3.3	19.6	7.3	15.9	7.3	19.5	8.3
Fussiness	severe	0.9	1.5	0.6	1.2	0.3	0.9	1.7	1.3
	any	42.3	29.4	46.8	27.7	38.2	22.9	27.7	19.5
Crying	severe	0	0	0	0.3	0.3	0.3	0	1.0
	any	27.7	18.4	34.7	17.5	23.0	15.0	17.0	14.4
Decreased Activity	severe	0.9	0.6	0	0	0	0	0	0
	any	44.9	13.4	29.9	9.6	13.9	7.3	12.0	4.4
Decreased Eating	severe	0	0.3	0	0	0	0	0.3	0
	any	29.2	11.9	19.3	16.9	15.2	14.1	13.3	14.1
Vomiting	severe	0	0	0	0	0	0	0	0
	any	6.8	7.4	5.7	4.5	3.3	4.0	4.0	4.0
Diarrhoea	severe	0.3	0	0	0	0	0	0	0.3
	any	9.2	13.1	4.8	6.6	7.0	8.3	7.0	7.1

Note: * interval of time in hours following vaccination
[‡] redness or swelling ≥35 mm
[§] fever ≥40.0 °C

In a clinical trial conducted in Sweden comparing three acellular pertussis vaccines and one whole-cell DPT vaccine, 20,745 infants received a “hybrid” formulation of TRIPACEL® which contained the same amounts of pertussis antigens as in PEDIACEL®, at 2, 4 and 6 or 3, 5 and 12 months of age. Rates of adverse events were less than or comparable to the rates in the other acellular pertussis vaccine and whole-cell DTP groups in this study. The rates of reports of fever >40.5°C and seizures or suspected seizures were significantly higher following whole-cell DTP than following acellular pertussis vaccines. Rates of hypotonic/hyporesponsive episodes were comparable, with 29 reports following administration of TRIPACEL®. No deaths or cases of encephalitis/acute encephalopathy, invasive bacterial infection, infantile spasms or anaphylactic reactions were reported within 48 hours of vaccination.

There are currently no clinical data to support administration of a fifth dose with PEDIACEL®. In a study conducted by the U.S. National Institutes of Health (NIH), thirteen different formulations of acellular pertussis vaccines combined with diphtheria and tetanus toxoids (DTaP), including TRIPACEL® (containing less PT and FHA than PEDIACEL®),

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were evaluated for safety and immunogenicity when administered at 2, 4, 6 and 18 months, and 4 – 6 years of age. In an analysis of fourth and fifth dose follow-up studies from this multicentre trial, entire limb swelling was reported in 20 children (2%) of 1,015 children who received four consecutive doses of the same DTaP. It was found that large injection site reactions occurred more frequently after the fifth dose of DTaP than after the previous fourth dose. No reports were received of entire limb swelling in 121 children who received a fifth dose of the same DTaP. In 146 recipients who received 5 doses with different DTaP vaccines, 4 (2.7%) children were reported to have such swelling. In all reports the swelling subsided spontaneously and completely, without sequelae.

The following have been reported in postmarketing experience with component acellular pertussis combination vaccines and other tetanus toxoid-, diphtheria toxoid-, acellular pertussis-, polio- and Hib-containing vaccines.

Application Site Disorders:

Very Rare (<1/10,000) The following have been reported following administration of tetanus and/or diphtheria toxoid and/or pertussis and/or Act-HIB[®]-containing vaccines:

granuloma or sterile abscess at vaccination site
painless circumferential limb swelling following booster doses which resolves spontaneously
oedema of the lower extremities with cyanosis or transient purpura

Body as a Whole - General Disorders:

Rare (< 1/1,000 to ≥ 1/10,000) hypotonic-hyporesponsive episodes*, high fever (>40.5°C), unusual high-pitched or inconsolable crying

Very Rare (<1/10,000) The following have been reported following administration of tetanus and/or diphtheria toxoid and/or pertussis and/or Act-HIB[®]-containing vaccines:

anaphylactic reaction

Central and Peripheral Nervous System Disorders:

Uncommon (< 1/100 to ≥ 1/1000) febrile convulsions

Very Rare (<1/10,000) The following have been reported following administration of tetanus and/or diphtheria toxoid and/or pertussis and/or Act-HIB[®]-containing vaccines:

peripheral neuropathies, demyelinating disease, encephalopathy with and without permanent intellectual and/or motor impairment, polyradiculopathies

* hypotonic-hyporesponsive episodes (infant appears pale, hypotonic (limp) and unresponsive) have not to date been associated with any permanent sequelae

As with any vaccine, there is the possibility that broad use of the vaccine could reveal rare adverse reactions not observed in clinical trials.

DOSAGE AND ADMINISTRATION

For primary immunisation of infants the following routine PEDIACEL® immunisation schedule is recommended: one 0.5 mL dose administered intramuscularly at 2, 4 and 6 months of age.

A booster dose of 0.5 mL may be administered at 15 to 20 months of age. PEDIACEL® may be used irrespective of whether a whole-cell or acellular DPT was used for the primary immunisation.

The vaccine should not be administered to persons after their seventh birthday (see Precautions).

Infants born prematurely whose clinical condition is satisfactory should be vaccinated according to their chronological age from birth.

Inspect for extraneous particular matter before use.

Shake the vial or syringe well to distribute uniformly the suspension before withdrawing dose. When administering a dose from a stoppered vial, do not remove either the stopper or the metal seal holding it in place. Once the vial has been opened, any of its contents not used immediately should be discarded. Aseptic technique must be used for withdrawal of the dose. Before injection, the skin over the site should be cleansed with a suitable germicide.

Administer the vaccine intramuscularly. The anterolateral thigh is the preferred site for vaccination in infants and children under 12 months of age. The deltoid region is an alternative site for vaccination in older children (those who have commenced walking). If any other vaccines are administered during the same visit, they must be given at separate sites and with separate syringes.

After insertion of the needle, ensure that the needle has not entered a blood vessel.

Needles should not be recapped and should be disposed of properly.

Product is for single use in one patient only. Discard any residue.

The parent or guardian of the child should be given a card recording the details of the immunisation. In addition, it is essential that the physician or nurse record the immunisation history in the permanent medical record of each patient. This permanent office record should contain the name of the vaccine, date given, dose, manufacturer and lot number.

DO NOT INJECT INTRAVENOUSLY.

This vaccine must not be mixed with other vaccines in the same syringe.

OVERDOSAGE

There have been no reports of overdosage.

PRESENTATION

Vial	1 x 0.5 mL (Single Dose)
	5 x 0.5 mL (Single Dose)
Syringe	1 x 0.5 mL (Single Dose)
	5 x 0.5 mL (Single Dose)

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MEDICINE CLASSIFICATION

Prescription Medicine

STORAGE

Store at 2° to 8°C. REFRIGERATE. DO NOT FREEZE. Do not use after expiry date.

MANUFACTURER

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