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ADACEL®-POLIO

TETANUS TOXOID, REDUCED DIPHTHERIA TOXOID AND ACELLULAR PERTUSSIS VACCINE ADSORBED COMBINED WITH INACTIVATED POLIOMYELITIS VACCINE

Suspension for injection
Intramuscular injection

DESCRIPTION

ADACEL®-POLIO (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed Combined with Inactivated Poliomyelitis Vaccine) is a sterile, uniform, cloudy, white suspension of tetanus and diphtheria toxoids and acellular pertussis vaccine adsorbed separately on aluminum phosphate, combined with inactivated poliomyelitis vaccine (vero cell origin) types 1, 2 and 3, and suspended in water for injection. The acellular pertussis vaccine is composed of five purified pertussis antigens (PT, FHA, PRN and FIM).

INDICATIONS AND CLINICAL USE

ADACEL®-POLIO is indicated for active booster immunization for the prevention of tetanus, diphtheria, pertussis (whooping cough) and poliomyelitis in persons 4 years of age and above.
In children 4 to 6 years of age, ADACEL®-POLIO may be considered as an alternative for the fifth dose of diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (DTaP-IPV).
Persons who have had tetanus, diphtheria or pertussis should still be immunized since these clinical infections do not always confer immunity.
Human Immunodeficiency Virus (HIV)-infected persons, both asymptomatic and symptomatic, should be immunized against tetanus, diphtheria and pertussis according to standard schedules.
ADACEL®-POLIO is not to be used for the treatment of disease caused by *Bordetella pertussis, Corynebacterium diphtheriae, Clostridium tetani* or poliomyelitis infections.

Pediatrics
ADACEL®-POLIO has been used in clinical studies in children as young as 3 years of age.

Geriatrics
ADACEL®-POLIO has been used in clinical studies in persons up to 91 years of age.

Tetanus Prophylaxis in Wound Management
The need for active immunization with a tetanus toxoid-containing preparation (such as Td Adsorbed vaccine, ADACEL® or ADACEL®-POLIO) with or without passive immunization with Tetanus Immune Globulin, depends on both the condition of the wound and the patient's vaccination history. (See DOSAGE AND ADMINISTRATION.)

CONTRAINDICATIONS

Hypersensitivity
Known systemic hypersensitivity reaction to any component of ADACEL®-POLIO or a life-threatening reaction after previous administration of the vaccine or a vaccine containing one or more of the same components are contraindications to vaccination. Because of uncertainty as to which component of the vaccine may be responsible, none of the components should be administered. Alternatively, such persons may be referred to an allergist for evaluation if further immunizations are considered.

Acute Neurological Disorders
Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of a previous dose of a pertussis-containing vaccine that is not attributable to another identifiable cause is a contraindication to administration of any pertussis-containing vaccine, including ADACEL®-POLIO.

WARNINGS AND PRECAUTIONS

General
Before administration of ADACEL®-POLIO, health-care providers should inform the recipient or parent or guardian of the recipient of the benefits and risks of immunization, inquire about the recent health status of the patient to be immunized, review the patient's history concerning possible hypersensitivity to the vaccine or similar vaccine, previous immunization history, the presence of any contraindications to immunization and comply with any local requirements regarding information to be provided to the patient/guardian before immunization.
It is extremely important that the recipient, parent or guardian be questioned concerning any signs or symptoms of an adverse reaction after a previous dose of vaccine. (See CONTRAINDICATIONS and ADVERSE REACTIONS.)
The rates and severity of adverse events in recipients of tetanus toxoid are influenced by the number of prior doses and level of pre-existing antitoxins.
As with any vaccine, ADACEL®-POLIO may not protect 100% of vaccinated persons.
Administration Route Related Precautions: Do not administer ADACEL®-POLIO by intravascular injection: ensure that the needle does not penetrate a blood vessel.
Intradermal or subcutaneous routes of administration are not to be utilized.
ADACEL®-POLIO should not be administered into the buttocks.
Febrile and Acute Disease: Vaccination should be postponed in cases of an acute or febrile disease. However, a disease with low-grade fever should not usually be a reason to postpone vaccination.

Hematologic
Because any intramuscular injection can cause an injection site hematoma in persons with any bleeding disorders, such as haemophilia or thrombocytopenia, or in persons on anticoagulant therapy, intramuscular injections with ADACEL®-POLIO should not be administered to such persons unless the potential benefits outweigh the risk of administration. If the decision is made to administer any product by intramuscular injection to such persons, it should be given with caution, with steps taken to avoid the risk of hematoma formation following injection.

Immune
The possibility of allergic reactions in persons sensitive to components of the vaccine should be evaluated. Hypersensitivity reactions may occur following the use of ADACEL®-POLIO even in persons with no prior history of hypersensitivity to the product components.

As with all other products, epinephrine hydrochloride solution (1:1,000) and other appropriate agents should be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs. Health-care providers should be familiar with current recommendations for the initial management of anaphylaxis in non-hospital settings, including proper airway management. For instructions on recognition and treatment of anaphylactic reactions, see the current edition of the Canadian Immunization Guide or visit the Health Canada website.
Immunocompromised persons (whether from disease or treatment) may not achieve the expected immune response. If possible, consideration should be given to delaying vaccination until after the completion of any immunosuppressive treatment. Nevertheless, vaccination of persons with chronic immunodeficiency, such as HIV infection, is recommended even if the immune response might be limited.

Neurologic
ADACEL®-POLIO should not be administered to individuals with progressive neurological disorder, uncontrolled epilepsy, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized.
A review by the US Institute of Medicine (IOM) found evidence for a causal relation between tetanus toxoid and both brachial neuritis and Guillain-Barré syndrome. If Guillain-Barré syndrome has occurred within 6 weeks of receipt of prior vaccine containing tetanus toxoid, the decision to give ADACEL®-POLIO or any vaccine containing tetanus toxoid should be based on careful consideration of the potential benefits and possible risks.

Pregnant Women
The effect of ADACEL®-POLIO on the development of the embryo and fetus has not been assessed. Limited post-marketing data is available following administration of ADACEL®-POLIO in pregnant women. Vaccination in pregnancy is not recommended unless there is a definite risk of acquiring pertussis. As the vaccine is inactivated, risk to the embryo or the fetus is improbable. The benefits versus the risks of administering ADACEL®-POLIO during pregnancy should be carefully evaluated when there is a high probable risk of exposure to a household contact or during an outbreak in the community.

Nursing Women
The effect of administration of ADACEL®-POLIO during lactation has not been assessed. As ADACEL®-POLIO is inactivated, any risk to the mother or the infant is improbable. However, the effect on breast-fed infants of the administration of ADACEL®-POLIO to their mothers has not been studied. The risks and benefits of vaccination should be assessed before making the decision to immunize a nursing woman.

ADVERSE REACTIONS

Clinical Trial Adverse Drug Reactions
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect rates observed in practice. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to vaccine use and for approximating rates of those events.
The safety of ADACEL®-POLIO has been evaluated in a total of 1,636 participants who received a single dose of ADACEL®-POLIO in 7 clinical trials (644 children 3 to 7 years of age, 992 adolescents and adults 11 to 60 years of age). Pain was the most common injection site reaction in all age groups. Most injection site reactions occurred within 3 days following vaccination. The most frequent systemic reaction was headache in adolescents and adults and tiredness in children. These reactions were usually transient and of mild to moderate intensity.
Table 1 presents the frequencies of the solicited injection site and systemic adverse events reported in 3 UK clinical trials in which children previously primed with 3 doses of PEDIACEL® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Combined with Inactivated Poliomyelitis Vaccine and *Haemophilus b* Conjugate Vaccine (Tetanus Protein – Conjugate)) or a whole-cell pertussis combination vaccine, received a pre-school booster dose of ADACEL®-POLIO at 3 to 5 years of age. In addition, adverse events of irritability (7.3%), injection site bruising (3.3%), injection site pruritus (2.7%) and dermatitis (1.3%) were reported within 7 days of vaccination in two of these studies.
In clinical trials in children ADACEL®-POLIO showed a comparable safety profile to that of ADACEL® [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed]. Therefore, the safety of ADACEL®-POLIO, in particular for use as a 4 to 6 years-old booster dose is further supported by a study conducted with ADACEL® in 298 children.
The frequency of the solicited injection site and systemic adverse events reported in a Canadian clinical trial in adolescents and adults are also presented in Table 1.

Table 1: Frequency (%) of Solicited Reactions Observed in Clinical Trials in Children, Adolescents and Adults, Following a Single Booster Dose of ADACEL®-POLIO

Solicited Reactions	Children 3 to 5 Years of Age* (N = 307)	Adolescents 12 to 18 Years of Age† (N = 350)	Adults 19 to 60 Years of Age† (N = 366)
Injection Site Reactions			
Pain	46.5 – 71.3	88.3	86.3
Swelling	20.4 – 34.0	21.2	16.7
Redness	35.7 – 48.7	17.5	23.0
Systemic Reactions			
Fever‡	7.0 – 12.7	14.2	2.7
Headache	N.S.	41.3	37.7
Nausea	N.S.	17.5	14.5
Diarrhea	7.6 – 10.0	5.4	15.8
Vomiting	2.5 – 6.7	3.2	2.5
Body Ache	N.S.	26.1	24.0
Sore or Swollen Joints	1.3	11.2	11.2
Tiredness	35.7 – 52.7	37.2	29.8
Chills	N.S.	17.5	11.2
Rash	7.0 – 8.7	N.S.	N.S.

* Adverse reactions reported within 7 days of vaccination. Range of frequencies across 3 UK studies.
† Adverse reactions reported within 14 days of vaccination
‡ Fever was defined as temperature ≥ 37.5°C in children, ≥ 38.0°C in adolescents and adults. Fever was solicited up to 7 days post-vaccination in children, up to 72 hours in adolescents and adults.
N.S. Not solicited

Post-Market Adverse Drug Reactions
The following additional adverse events have been spontaneously reported during the post-marketing use of ADACEL®-POLIO. Because these events are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Blood and Lymphatic Disorders
Lymphadenopathy

Immune System Disorders
Anaphylactic reactions, such as urticaria, face edema and dyspnea

Nervous System Disorders
Convulsions, vasovagal syncope, Guillain-Barré syndrome, facial palsy, myelitis, brachial neuritis, transient paresthesia/ hypoesthesia of vaccinated limb, dizziness

Musculoskeletal and Connective Tissue Disorders
Pain in vaccinated limb

General Disorders and Administration Site Conditions
Extensive limb swelling, which may extend from the injection site beyond one or both joints and is frequently associated with erythema, and sometimes with blisters, has been reported following administration of ADACEL®-POLIO. The majority of these reactions appeared within 48 hours of vaccination and spontaneously resolved over an average of 4 days without sequelae. The risk appears to be dependent on the number of prior doses of d/DTaP vaccine, with a greater risk following the 4th and 5th doses.
Malaise, pallor, injection site induration

DRUG INTERACTIONS

Vaccine-Drug Interactions
Immunosuppressive treatments may interfere with the development of the expected immune response. (See WARNINGS AND PRECAUTIONS.)

Concomitant Vaccine Administration
ADACEL®-POLIO may be administered concurrently with a dose of hepatitis B vaccine. Supportive data from a study conducted with ADACEL® suggests that ADACEL®-POLIO may be used concomitantly with trivalent influenza vaccine. ADACEL®-POLIO has been safely administered concomitantly with measles-mumps-rubella vaccine in non-controlled clinical studies in children 3 to 5 years of age. Data are not available on concomitant use of ADACEL®-POLIO and varicella vaccine.
Administering the most widely used live and inactivated vaccines during the same patient visit has produced seroconversion rates and rates of adverse reactions similar to those observed when the vaccines are administered separately. Vaccines administered concomitantly should be given using separate syringes at separate sites. Simultaneous administration is suggested, particularly when there is concern that a person may not return for subsequent vaccination.
ADACEL®-POLIO should not be mixed in the same syringe with other parenterals.

DOSAGE AND ADMINISTRATION

Recommended Dose
ADACEL®-POLIO should be administered as a single injection of 1 dose (0.5 mL) by the intramuscular route. The preferred site is the deltoid muscle.
Fractional doses (doses <0.5 mL) should not be given. The effect of fractional doses on safety and efficacy has not been determined.
Health-care professionals should refer to the National Advisory Committee on Immunization (NACI) guidelines for tetanus prophylaxis in routine wound management shown in Table 2.

Table 2: NACI Recommended Use of Immunizing Agents in Wound Management

History of Tetanus Immunization	Clean, minor wounds		All other wounds	
	Td*	TIG† (Human)	Td*	TIG† (Human)
Uncertain or <3 doses of an immunization series‡	Yes	No	Yes	Yes
≥ 3 doses received in an immunization series‡	No§	No	No**	No ††

* Adult-type tetanus and diphtheria toxoid.
† Tetanus immune globulin, given at a separate site from the Td.
‡ Primary immunization is at least 3 doses at age appropriate intervals.
§ Yes, if >10 years since last booster.
** Yes, if >5 years since last booster.
†† Yes, if persons are known to have a significant humoral immune deficiency state (e.g., HIV, agammaglobulinemia) since immune response to tetanus toxoid may be suboptimal.

A thorough attempt must be made to determine whether a patient has completed primary immunization. Persons who have completed primary immunization against tetanus and who sustain wounds that are minor and uncontaminated, should receive a booster dose of a tetanus toxoid-containing preparation if they have not received tetanus toxoid within the preceding 10 years. For tetanus-prone wounds (e.g., wounds contaminated with dirt, feces, soil and saliva, puncture wounds, avulsions and wounds resulting from missiles, crushing, burns or frostbite), a booster is appropriate if the patient has not received a tetanus toxoid-containing preparation within the preceding 5 years.
For adults who have not previously received a dose of acellular pertussis vaccine, a single Tetanus-diphtheria (Td) booster dose should be replaced by a combined tetanus-diphtheria-acellular pertussis vaccine (Tdap).

Administration
Inspect for extraneous particulate matter and/or discolouration before use. (See DESCRIPTION.) If these conditions exist, the product should be discarded.
Shake the vial or syringe well until a uniform, cloudy, suspension results. When administering a dose from a stoppered vial, do not remove either the stopper or the metal seal holding it in place. Use a separate sterile needle and syringe, or a sterile disposable unit for each individual patient to prevent disease transmission. Needles should not be recapped but should be disposed of according to biohazard waste guidelines.
Before injection, the skin over the site to be injected should be cleansed with a suitable germicide. Administer the total volume of 0.5 mL **intramuscularly** (IM). The preferred site of injection is the deltoid muscle.

STORAGE AND STABILITY

Store at 2° to 8°C (35° to 46°F). **Do Not Freeze.** Discard product if exposed to freezing.
Do not use after expiration date.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Dosage Forms
ADACEL®-POLIO is supplied as a sterile, uniform, cloudy, white suspension in a vial or prefilled syringe.

Composition
Each dose (0.5 mL) is formulated to contain:

Active Ingredients		Other Ingredients	
Tetanus Toxoid	Not less than 20 International Units (5 Lf)	*Excipients*	
Diphtheria Toxoid	Not less than 2 International Units (2 Lf)	Aluminum Phosphate (adjuvant)	1.5 mg
Acellular Pertussis:		2-phenoxyethanol	0.6% v/v
Pertussis Toxoid (PT)	2.5 µg	Polysorbate 80	<5 µg
Filamentous Haemagglutinin (FHA)	5 µg	Water for Injection	q.s. 0.5 mL
Pertactin (PRN)	3 µg		
Fimbriae Types 2 and 3 (FIM)	5 µg		
Inactivated Poliomyelitis Vaccine			
Type 1 (Mahoney)	40 D-antigen units*		
Type 2 (MEF-1)	8 D-antigen units*		
Type 3 (Saukett)	32 D-antigen units*		

* or the equivalent antigen quantity, determined by suitable immunochemical method

Manufacturing Process Residuals
Bovine serum albumin, formaldehyde, glutaraldehyde, streptomycin, neomycin and polymyxin B are present in trace amounts.

Packaging
ADACEL®-POLIO is presented as a suspension for injection in pre-filled syringes or vials (0.5 mL):
1 single dose vial
5 single dose vials
10 single dose vials
1 single dose syringe without attached needle and with or without 2 separate needles (1 x 25G x 16mm and 1 x 23G x 25mm)
10 single dose syringes without attached needles and with or without 2 separate needles (5 x 25G x 16mm and 5 x 23G x 25mm)
20 single dose syringes without attached needles
The vials and syringes are made of USP Type 1 glass. The container closure system for all presentations of ADACEL®-POLIO is free of latex (natural rubber).
Not all pack sizes may be marketed.
Product information as of August 2011.
Manufactured by: **Sanofi Pasteur Limited** - Toronto, Ontario, Canada

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