For the use only of a Registered Medical Practitioner only

Abridged Prescribing Information

Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed
ADACEL®

COMPOSITION:

Each 0.5mL contains:
Tetanus Toxoid Adsorbed .....5 Lf
Diphtheria Toxoid Adsorbed .....2 Lf
Pertussis Toxoid Adsorbed (PT) .....2.5 micrograms (µg)
Filamentous Haemagglutinin Adsorbed (FHA) .... 5.0 micrograms (µg)
Pertactin Adsorbed (PRN) ..... 3.0 micrograms (µg)
Fimbriae Types 2 and 3 Adsorbed (FIM) ..... 5.0 micrograms (µg)
Aluminium Phosphate (Adjuvant) .....1.5 milligram (mg)
2-Phenoxyethanol ..... 0.6 %v/v
Formaldehyde ..... 5.0000 micrograms (µg)
Glutaraldehyde-Trace Amounts
Water for Injection .....q.s. 0.5 ml

THERAPEUTIC INDICATIONS:

ADACEL® is indicated for active booster immunization for the prevention of tetanus, diphtheria and pertussis (whooping cough) as a single dose in persons aged 11 to 54 years.
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® is not to be used for the treatment of disease caused by *B. pertussis, C. diphtheriae or C. tetani infections*.

Other Populations:
ADACEL® is not indicated for immunization of children below the age of 11 years and in persons above the age of 54 years.

POSOLOGY & METHOD OF ADMINISTRATION:

Dosing Considerations
Administration Route Related Precautions:
Do not administer ADACEL® 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® should not be administered into the buttocks.

Recommended Dose and Dosage Adjustment
ADACEL® (0.5 mL) should be administered as a booster injection by the intramuscular route.
Re-dosing with ADACEL® can be used to boost immunity to diphtheria, tetanus and pertussis at 5- to10-year intervals.

The preferred site is into the deltoid muscle. Fractional doses (doses <0.5 mL) should not be given. The effect of fractional doses on the safety and efficacy has not been determined.

ADACEL® may be administered to pregnant women during the second or third trimester to provide passive protection of infants against pertussis (see Special Populations & Pharmacodynamics)

SAFETY RELATED INFORMATION:

CONTRAINDICATIONS:

ADACEL® is contraindicated in patients who are hypersensitive to this vaccine or to a vaccine containing one or more of the same components after previous administration (because of uncertainty as to which component of the vaccine may be responsible, none of the components should be administered) or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see DOSAGE FORMS, COMPOSITION & PACKAGING.

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 not attributable to another identifiable cause is a contraindication to vaccination with any pertussis-containing vaccine, including ADACEL®.

PREGNANCY AND LACTATION:

ADACEL® can be used during the second or third trimester of pregnancy in accordance with official recommendations (see POSOLOGY & METHOD OF ADMINISTRATION).

Breast-feeding
It is not known whether the active substances included in ADACEL® are excreted in human milk but antibodies to the vaccine antigens have been found to be transferred to the suckling offspring of rabbits. Two animal developmental studies conducted in rabbits have not shown any harmful effects of maternal antibodies induced by the vaccine on offspring postnatal development.

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

SPECIAL WARNING AND PRECAUTIONS:

General: ADACEL® is not to be used for the treatment of disease caused by *Bordetella pertussis, Corynebacterium diphtheriae* or *Clostridium tetani* infections.
Syncope (fainting) can occur following, or even before, administration of injectable vaccines, including ADACEL®. Procedures should be in place to prevent falling injury and manage syncopal reactions.

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® should not be administered to such persons unless the potential benefits outweigh the risk of administration.
Immune: The possibility of allergic reactions in persons sensitive to components of the vaccine should be evaluated.
Neurologic: ADACEL® should not be administered to individuals with progressive or unstable neurological disorders, uncontrolled epilepsy or progressive encephalopathy until a treatment regimen has been established, the condition has stabilized, and the benefit clearly outweighs the risk.
Skin: Local reactions at injection site such as pain, swelling and erythema/redness may occur. See ADVERSE REACTIONS.

UNDESIRABLE REACTIONS:

Pain at the injection site was the most common solicited injection site reaction. Most injection site reactions occurred within 3 days following vaccination and their mean duration was less than 3 days. The most frequent systemic reaction was tiredness in children and headache in adolescents and adults (18-64 years). Myalgia was the most frequently reported systemic reaction among older adults ≥65 years of age. Fever was reported in less than 10% of vaccinees. These reactions were usually transient and of mild to moderate intensity. The following additional adverse events have been spontaneously reported during the post- marketing use of ADACEL®. ***Immune System Disorders*** Hypersensitivity (anaphylactic) reaction (angioedema, edema, rash, hypotension) ***Nervous System Disorders*** Paraesthesia, hypoesthesia, Guillain- Barré syndrome, brachial neuritis, facial palsy, convulsion, syncope, myelitis, ***Cardiac Disorders*** Myocarditis, ***Skin and Subcutaneous Tissue Disorders*** Pruritus, urticaria; ***Musculoskeletal and Connective Tissue Disorders*** Myositis, muscle spasm; ***General Disorders and Administration Site Conditions*** Large injection site reactions (>50 mm) and extensive limb swelling from the injection site beyond one or both joints have been reported after administration of ADACEL® in adolescents and adults. Injection site bruising, injection site nodule, sterile abscess.

For full prescribing information, please contact Sanofi Healthcare India Pvt. Ltd., Sanofi House, C.T.S No. - 117-B, L & T Business Park, Saki Vihar Road, Powai, Mumbai 400072.

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