For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory

Abridged Prescribing Information

TETANUS TOXOID, REDUCED DIPHTHERIA TOXOID AND ACELLULAR PERTUSSIS VACCINE ADSORBED
ADACEL®
COMPOSITION
Each single dose (0.5 mL) contains:

Active Ingredients	
Tetanus Toxoid	5 Lf
Diphtheria Toxoid	2 Lf
Acellular Pertussis	
Pertussis Toxoid (PT)	2.5 µg
Filamentous Haemagglutinin (FHA)	5 µg
Pertactin (PRN)	3 µg
Fimbriae Types 2 and 3 (FIM)	5 µg

Excipients: Aluminum Phosphate (adjuvant) 1.5 mg ,2-phenoxyethanol 0.6% v/v, Manufacturing Process Residuals, and glutaraldehyde are present in trace amounts.

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. In accordance with local recommendations, ADACEL® may be considered as an alternative for the fifth dose of tetanus, diphtheria and acellular pertussis vaccine (DTaP) in children 4 to 6 years of age, concomitantly administered with Inactivated Poliomyelitis Vaccine (IPV), at separate sites to complete the vaccination series for this age, when indicated. 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

DOSAGE AND ADMINSITRATION
ADACEL® is supplied as a sterile uniform, cloudy, white suspension in a vial. The immunization schedule with ADACEL® should follow local recommendations. ADACEL® should be administered as a single injection of 1 dose (0.5 mL) by the intramuscular route. The preferred site is into the deltoid muscle. Do not administer into the buttocks. Fractional doses (doses <0.5 mL) should not be given

SAFETY RELATED INFORMATION:
CONTRAINDICATIONS
- Known systemic hypersensitivity reaction to any component of ADACEL® or a life-threatening reaction after previous administration of the vaccine or a vaccine containing one or more of the same components
- Acute Neurological Disorders
- Encephalopathy (e.g., coma, decreased level of consciousness,prolonged seizures) within 7 days of a previous dose of apertussis-containing vaccine not attributable to another identifiablecause is a contraindication to vaccination with any pertussiscontaining vaccine, including ADACEL®.

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PREGNANCY AND LACTATION

Vaccination in pregnancy is not recommended unless there is a definite risk of acquiring pertussis. The benefits versus the risks of administering ADACEL® during pregnancy and lactation should be carefully evaluated when there is a high probable risk of exposure to a household contact or during an outbreak in the community.

WARNING AND PRECAUTIONS

Do not administer ADACEL® by intravascular injection, intradermal or subcutaneous routes.

Vaccination should be postponed in case of acute or febrile disease. Because any intramuscular injection can cause an injection site hematoma in persons with any bleeding disorders, such as hemophilia 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. Hypersensitivity reactions may occur following the use of ADACEL® even in persons with no prior history of hypersensitivity to the product components. Immunocompromised persons (whether from disease or treatment) may not achieve the expected immune response. 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. If GBS occurred within 6 weeks of receipt of prior vaccine containing tetanus toxoid, the decision to give ADACEL® or any vaccine containing tetanus toxoid should be based on careful consideration of the potential benefits and possible risks.

ADVERSE 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. 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.

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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