Tetanus and Diphtheria Toxoids Adsorbed Combined with Component Pertussis Vaccine

Adacel

Product: Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (ADACEL®)
Strength: 0.5 mL Suspension for Injection for Intramuscular Injection in Glass Vial
Presentation: 0.5 mL Type 1 single-dose glass vial, free of latex (Box of 1 or 5)
I: Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed – For the active booster immunization on the prevention of tetanus, diphtheria and pertussis (whooping cough) in persons 4 years of age and older. Can be used during pregnancy for passive immunization against pertussis disease in young infants. 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 through 6 years of age, concomitantly administered with Inactivated Poliomyelitis Vaccine (IPV) at separate sites to complete the vaccination series for this age, when indicated.
C: 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. 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®.
W/P: Syncope (fainting) can occur following, or even before, administration of injectable vaccines, thus procedures should be in place to prevent falling injury and manage syncopal reactions. Vaccination should be postponed in cases of an acute or febrile disease. However, a disease with low-grade fever should not be a reason to postpone vaccination. Immunocompromised persons 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. 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 Guillain-Barré syndrome 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.
Interactions: Immunosuppressive treatments may interfere with the development of the expected immune response. ADACEL® may be administered concurrently with a dose of trivalent inactivated influenza vaccine and with a dose of hepatitis B vaccine in 11- to 12-year-olds. Vaccines administered simultaneously should be given using separate syringes at separate injection sites and preferably in separate limbs. ADACEL® should not be mixed in the same syringe with other parenteral.
AE: Pain or swelling at the injection site, tiredness, headache, myalgia, erythema
PK/ PD: ADACEL®, is a sterile, uniform, cloudy, white suspension of tetanus and diphtheria toxoids adsorbed separately on aluminum phosphate, combined with acellular pertussis vaccine and suspended in water for injection. The acellular pertussis vaccine is composed of 5 purified pertussis antigens (PT, FHA, PRN and FIM). In a clinical trial in Sweden (Sweden I Efficacy Trial), the same pertussis components as in ADACEL® (i.e., PT, FHA, PRN and FIM) have been shown to prevent pertussis in infants with a protective efficacy of 85.2% using the World Health Organization (WHO) case definition (≥21 consecutive days of paroxysmal cough with culture or serologic confirmation or epidemiological link to a confirmed case). In the same study, the protective efficacy against mild disease was 77.9%. In ADACEL® clinical trials, in children, adolescents and adults <65 years of age, postvaccination Geometric Mean Concentrations (GMCs) for all pertussis antibodies were consistently above those of TRIPACEL® in the Sweden I Efficacy Trial. Older adults (≥65 years of age) vaccinated with a single dose of ADACEL® achieved lower GMCs for some of the pertussis antibodies than did infants who had received 3 or 4 doses of TRIPACEL®. Nevertheless, their post-immunization anti-pertussis antibody levels were 4.4- to 15.1-fold higher than pre-immunization levels, suggested an improved degree of protection agasinst pertussis.

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