

April 2014

Dear Health Care Provider:

I am pleased to inform you that on March 31, 2014, the Food and Drug Administration (FDA) expanded the approved age indication of Adacel[®] (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed) (Tdap) for active booster immunization for the prevention of tetanus, diphtheria, and pertussis as a single dose in persons 10 through 64 years of age.

At a time when we continue to see a rise in reported pertussis incidence, this approval not only reinforces the safety and efficacy profiles of Adacel vaccine, but it also provides an additional opportunity to administer Adacel vaccine to a younger age group to help prevent this highly contagious disease.

Adacel vaccine was originally licensed by the FDA in June 2005 as the first booster to address pertussis protection for both adolescents and adults. Adacel vaccine provides demonstrated immunogenicity against tetanus, diphtheria, and pertussis, and its safety profile is similar to that of tetanus and diphtheria (Td) vaccine.

We look forward to continuing to partner with you to meet your vaccination needs. Should you have any questions or require additional information, please contact your sales representative or call a customer account representative at 1-800-VACCINE (1-800-822-2463).

IMPORTANT SAFETY INFORMATION

Indication

Adacel vaccine is indicated for active booster immunization against tetanus, diphtheria, and pertussis. Adacel vaccine is approved for use as a single dose in individuals 10 through 64 years of age.

Safety Information

The most common local and systemic adverse reactions to Adacel vaccine include pain, erythema, and swelling at the injection site; headache, body ache or muscle weakness, and tiredness. Other adverse reactions may occur. A known hypersensitivity (eg, anaphylaxis) after a previous dose of Adacel vaccine or any other tetanus toxoid, diphtheria toxoid, or pertussis antigen-containing vaccine, or to any component; or encephalopathy within 7 days of a previous dose of a pertussis antigen-containing vaccine, is a contraindication.

If Guillain-Barré syndrome or brachial neuritis has occurred within 6 weeks of previous vaccination with a tetanus toxoid-containing vaccine, if progressive or unstable neurologic disorders exist, or if adverse events have occurred in temporal relation to receipt of pertussis antigen-containing vaccine, the decision to give Adacel vaccine should be based on careful consideration of the potential benefits and risks. Persons who experienced an Arthus-type hypersensitivity reaction following a prior dose of tetanus toxoid-containing vaccine should not receive Adacel vaccine unless at least 10 years have elapsed since the last dose of tetanus toxoid-containing vaccine. Syncope (fainting) can occur in association with administration of injectable vaccines, including Adacel vaccine. Procedures should be in place to prevent falling injury and manage syncopal reactions. The tip caps of

the prefilled syringes may contain natural rubber latex that may cause allergic reactions in latex-sensitive individuals. Vaccination with Adacel vaccine may not protect all individuals.

Before administering Adacel vaccine, [click here](#) to view the full Prescribing Information.

Sincerely,



David Greenberg, MD
Vice President, Scientific and Medical Affairs and Chief Medical Officer
Sanofi Pasteur US