BOOSTRIX®
[Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap)]

Whooping Cough (Pertussis) Booster Vaccine for Adolescents (10-18) and Adults

- BOOSTRIX® [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap)], manufactured by GlaxoSmithKline (GSK), is a vaccine for active booster immunization against tetanus, diphtheria and pertussis (whooping cough).
- BOOSTRIX is the first Tdap vaccine approved in the U.S. for use in adults 65 years of age and older. BOOSTRIX is approved in the U.S. for use as a single dose in individuals 10 years of age and older, the broadest age range for any Tdap vaccine.

About Pertussis, Diphtheria, Tetanus

- **Pertussis**, also known as "whooping cough," is a highly contagious respiratory disease characterized by severe coughing fits. Whooping cough may lead to complications, such as pneumonia or rib fracture.
- **Diphtheria** is a bacterial disease that primarily affects the tonsils and the throat. It is usually spread when an infected person coughs or sneezes. It can lead to breathing and heart problems.
- **Tetanus** (lockjaw) is a bacterial disease that can cause muscle stiffness and spasms, often starting in the muscles of the jaw and neck. The bacteria that causes tetanus can enter the body through cuts, scratches or wounds in the skin.

Proven Safety and Immunogenicity

- The approval of BOOSTRIX for use in adults 65 years of age and older was based on two clinical trials in which more than 1,100 U.S. subjects received BOOSTRIX.

Important Safety Information

- In clinical studies, common adverse events were injection-site reactions (pain, redness, swelling and increase in arm circumference), headache, fatigue and gastrointestinal symptoms
- Severe allergic reaction after a previous dose of any tetanus toxoid-, diphtheria toxoid- or pertussis antigen-containing vaccine, or to any component of BOOSTRIX, or encephalopathy within seven days of a previous pertussis antigen-containing vaccine is a contraindication
- BOOSTRIX is available in vials and 2 types of pre-filled syringes. One type of pre-filled syringe has a tip cap, which may contain natural rubber latex and a plunger which does not contain latex. The other type has a tip cap and a rubber plunger which contain dry natural latex rubber. Use of these syringes may cause allergic reactions in latex sensitive individuals. The vial stopper does not contain latex
- The decision to give BOOSTRIX should be based on benefits and risks if Guillain-Barré syndrome occurred within six weeks of receipt of a prior tetanus toxoid-containing vaccine
- Progressive or unstable neurologic conditions are reasons to defer vaccination with a pertussis-containing vaccine, including BOOSTRIX
- Persons who experienced an Arthus-type hypersensitivity reaction following a prior dose of tetanus toxoid-containing vaccine should not receive BOOSTRIX unless 10 years have elapsed since the last dose of a tetanus toxoid-containing vaccine
- BOOSTRIX may not protect 100 percent of individuals receiving the vaccine

GlaxoSmithKline Biologicals

GlaxoSmithKline Biologicals (GSK Biologicals), GlaxoSmithKline's vaccines business, is one of the world's leading vaccine companies and a leader in innovation. The company is active in vaccine research, development and production with over 30 vaccines approved for marketing and 20 more in development - both in the prophylactic and therapeutic fields. Headquartered in Belgium, GSK Biologicals has 14 manufacturing sites strategically positioned around the globe. In 2010, GSK Biologicals distributed 1.43 billion doses of vaccines to 179 countries in both the developed and the developing world.

Through its accomplished and dedicated workforce, GSK Biologicals applies its expertise to the discovery of innovative vaccines that contribute to the health and well-being of people of all generations around the world.