VAXELIS® (Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, Haemophilus b Conjugate and Hepatitis B Vaccine)

VAXELIS is a vaccine indicated for active immunization to prevent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and invasive disease due to *Haemophilus influenzae* type b (Hib). VAXELIS is approved for use as a 3-dose series in children 6 weeks through 4 years of age (prior to the 5th birthday).

IMPORTANT SAFETY INFORMATION

Do not administer VAXELIS to anyone with a history of severe allergic reaction to a previous dose of VAXELIS, any ingredient of VAXELIS, or any other diphtheria toxoid, tetanus toxoid, pertussis-containing vaccine, inactivated poliovirus vaccine, hepatitis B vaccine, or Hib vaccine.

Do not administer VAXELIS to anyone with a history of encephalopathy within 7 days of a pertussis-containing vaccine with no other identifiable cause.

Do not administer VAXELIS to anyone with a history of progressive neurologic disorder until a treatment regimen has been established and the condition has stabilized.

Carefully consider benefits and risks before administering VAXELIS to persons with a history of: fever ≥40.5°C (≥105°F), hypotonic-hyporesponsive episode (HHE), or persistent, inconsolable crying lasting ≥3 hours within 48 hours after a previous pertussis-containing vaccine; and/or seizures within 3 days after a previous pertussis-containing vaccine.

If Guillain-Barré syndrome occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following VAXELIS.

Apnea following intramuscular vaccination has been observed in some infants born prematurely. Consider the individual infant's medical status and potential benefits and possible risks of intramuscular vaccination in deciding when to administer VAXELIS to an infant born prematurely.

Vaccination with VAXELIS may not protect all individuals.

The solicited adverse reactions 0-5 days following any dose were irritability (≥55%), crying (≥45%), injection site pain (≥44%), somnolence (≥40%), injection site erythema (≥25%), decreased appetite (≥23%), fever ≥38.0°C (≥19%), injection site swelling (≥18%), and vomiting (≥9%).

The 3-dose immunization series consists of a 0.5 mL intramuscular injection, administered at 2, 4, and 6 months of age.

A 3-dose series of VAXELIS does not constitute a primary immunization series against pertussis; an additional dose of pertussis-containing vaccine is needed to complete the primary series.

Before administering VAXELIS, please read the accompanying Prescribing Information. The Patient Product Information also is available.