VAXELIS®

DTaP/ IPV/Hib/Hep B

Pathophysiology	**See DTaP, IPV, Hib, and Hepatitis B information**
Vaccine Description	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. VAXELIS is approved for use as a 3-dose series in children from 6 weeks through 4 years of age (prior to the 5th birthday).
Dose & Route	0.5 mL IM injection
Administration Schedule	**Dose** **Recommended Age** 1 .....2 months 2.....4 months 3.....6 months
Minimum Intervals	**Dose** **Minimum Interval and Ages** 1 ……6 weeks of age 2 ……4 weeks after dose 1 (10 weeks of age) 3 ……8 weeks after dose 2 *and* 16 weeks after dose 1 *and* at least 24 weeks of age
Contraindications	-Severe allergic reaction (e.g., anaphylaxis) 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 Haemophilus influenzae type b vaccine. -Encephalopathy within 7 days of a previous pertussis-containing vaccine with no other identifiable cause -Progressive neurologic disorder until a treatment regimen has been established and the condition has stabilized
Precautions	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. -Seizures within 3 days after a previous pertussis-containing vaccine. -If Guillain-Barre' syndrome occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the risk for GBS may be increased following VAXELIS. -Apnea following intramuscular vaccination has been observed in some infants born prematurely vaccination should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination. -Urine antigen detection may not have definitive diagnostic value in suspected H. influenzae type b disease following vaccination with VAXELIS.
Special Instructions	VAXELIS should not be used for the fourth or fifth dose for the DTaP series. However, if VAXELIS is inadvertently given for either booster dose, the dose does not need to be repeated with another DTaP-containing vaccine when the proper spacing of previous doses is maintained. -VAXELIS is not indicated for the fourth dose of the IPV series. However, if VAXELIS is inadvertently given for the booster dose, the dose does not need to be repeated with another IPV-containing vaccine when the proper spacing of previous doses is maintained. -VAXELIS is not licensed for the birth dose but can be used for doses given at age > 6 weeks to infants of HBs Ag-negative mothers, HBs Ag-positive mothers, or HBs Ag status unknown. For adequate immune response, the last dose of HepB vaccine should be given at >24 weeks; therefore, the third dose of VAXELIS is not recommended to be given before age 24 weeks. If it is given earlier, an additional dose of HepB vaccine should be given at age > 24 weeks, maintaining proper spacing with previous dose. -Monovalent PRP-OMP Hib vaccines are licensed as a 2-dose primary series at ages 2 and 4 months. VAXELIS is licensed as a 3-dose primary series. Therefore, 3 doses of a Hib conjugate-containing vaccine are needed to complete the primary series if VAXELIS is used for any doses. VAXELIS should not be used for the booster dose (after completion of the 3-dose primary series). Any Hib conjugate vaccine licensed for a booster dose can be used, but if VAXELIS is inadvertently given for the booster dose, the dose does not need to be repeated when proper spacing of previous doses is maintained.