Vaxelis™

Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, Haemophilus b Conjugate and Hepatitis B Vaccine

VAXELIS helps simplify the execution of the vaccination schedule with 2-3 fewer shots[1-4]

VAXELIS is the first-and-only hexavalent vaccine approved by the FDA[5]

- Aligns with the CDC-recommended pediatric immunization schedule[4,5]
- Minimizes the number of injections over the series of primary visits—2, 4, and 6 months of age[1-4]
- Preservative-free formulation available in both prefilled syringes and single-dose vials with no reconstitution required
- May reduce tasks associated with coding and billing—with 1 NDC code instead of 2[6]

Supplied	Code
Single-dose vial 0.5 mL	NDC 63361-243-58
Package of 10 single-dose vials 0.5 mL	NDC 63361-243-10
Single-dose prefilled syringe 0.5 mL	NDC 63361-243-88
Package of 10 single-dose prefilled syringes 0.5 mL	NDC 63361-243-15

CDC, Centers for Disease Control and Prevention; NDC, National Drug Code.

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 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.

Important Safety Information continued on next page.

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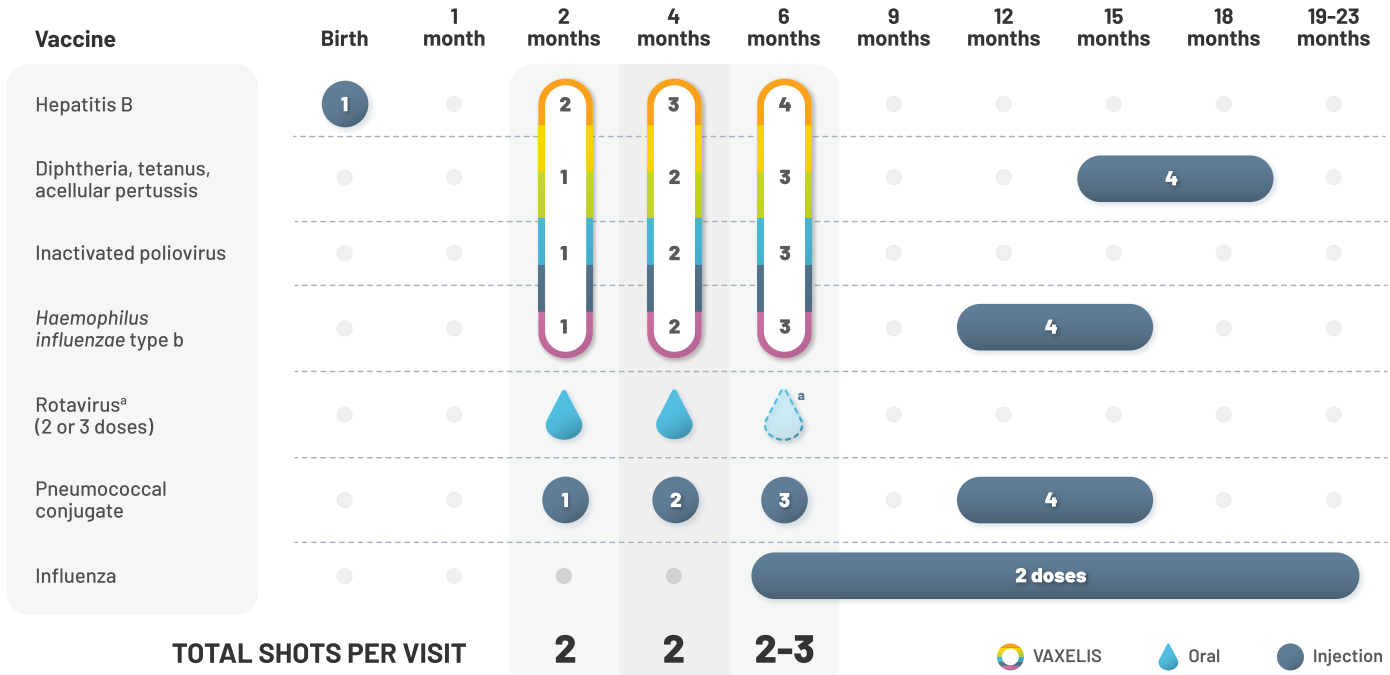
VAXELIS requires fewer injections compared to pentavalent vaccines (+ hep B or Hib vaccine)[1-4]

VAXELIS[4,5]



[a]Oral rotavirus vaccine may be administered as a 2-dose series (at 2 and 4 months) or a 3-dose series (at 2, 4, and 6 months), depending on brand.[4]
Hep B, hepatitis B; Hib, *Haemophilus influenzae* type b.

Important Safety Information *(continued)*

- 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 Information also is available.

References: 1. Pentacel. Prescribing Information: Sanofi Pasteur; 2020. Accessed February 6, 2021. https://www.vaccineshoppe.com/image.cfm?doc_id=13799&image_type=product_pdf. **2.** Pentacel. Prescribing Information: Sanofi Pasteur; 2019. Accessed February 6, 2021. https://www.vaccineshoppe.com/mailing/VSH/Pls%20&%20SDS/PI/dtppv-fplr-sl-dec19.pdf. **3.** PEDIARIX. Prescribing Information. GlaxoSmithKline, Inc.; 2019. Accessed February 6, 2021. https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Pediarix/pdf/PEDIARIX.PDF. **4.** Centers for Disease Control and Prevention. Recommended child and adolescent immunization schedule for ages 18 years or younger, United States, 2021. Last reviewed February 12, 2021. Accessed February 16, 2021. https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf. **5.** Oliver SE, Moore KL. Licensure of a diphtheria and tetanus toxoids and acellular pertussis, inactivated poliovirus, *Haemophilus influenzae* type b conjugate, and hepatitis B vaccine, and guidance for use in infants. *MMWR Morb Mortal Wkly Rep*. 2020;69(5):136–139. doi:10.15585/mmwr.mm6905a5. **6.** Pellissier JM, Coplan PM, Jackson LA, May JE. The effect of additional shots on the vaccine administration process: results of a time-motion study in 2 settings. *Am J Manag Care*. 2000;6(9):1038–1044.

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