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

Administration, storage, and handling for VAXELIS

A fully liquid vaccine formulation like VAXELIS may reduce vaccine prep time[1-2]

Administration of VAXELIS

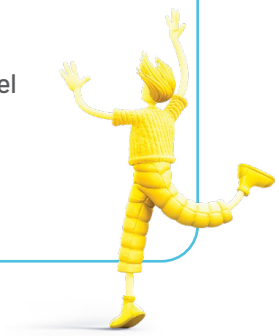
- Just before use, shake the vial or prefilled syringe until the suspension is uniform, white, and cloudy.
- Inspect the vial or prefilled syringe for particulate matter or discoloration. If you notice either, do not administer the vaccine.
- Administer the single 0.5 mL dose of VAXELIS intramuscularly.
  - In infants younger than 1 year, the anterolateral aspect of the thigh is the preferred site of injection. The vaccine should not be injected into the gluteal area.
- Discard unused portion.

Do not combine VAXELIS through reconstitution or mix with any other vaccine.

Storage information for VAXELIS

Here are some key things to keep in mind when storing VAXELIS:

- VAXELIS is supplied in a single-dose vial in packages of 10 vials or in a single-dose, prefilled syringe in packages of 10 syringes
- Store at 2°C to 8°C (36°F to 46°F)
- DO NOT freeze VAXELIS. Product which has been exposed to freezing temperatures should not be used
- Protect from light
- Do not use VAXELIS after the expiration date shown on the label



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.

(Important Safety Information continues on the next page)

SEE NEXT PAGE FOR MORE INFORMATION

Ready to order VAXELIS?

VAXELIS can be ordered directly from Sanofi
- Call 1-800-VACCINE
- Visit **VaccineShoppe.com**
- Contact your Sanofi representative

VAXELIS is available through authorized wholesalers or distributors
- Contact your Sanofi representative or contracting organization
- Visit **VAXELIScontract.com** for a list of Authorized Distributors

When you're ready to restock, you can visit VaccineShoppe.com

Important Safety Information *(continued)*

- 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 Information also is available.

References: 1. Pentacel. Prescribing Information. NDC No. 49281-510-05. Sanofi Pasteur; 2022. **2.** De Coster I, Fournie X, Faure C, et al. Assessment of preparation time with fully-liquid versus non-fully liquid pediatric hexavalent vaccines. A time and motion study. *Vaccine.* 2015;33(32):3976-3982. doi:10.1016/j.vaccine.2015.06.030

Copyright © 2023 MSP Vaccine Company. All rights reserved. US-VAX-00893 04/23

MERCK sanofi

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