

Patient Information

VAXELIS™ (pronounced "vak-sel-lis")

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

Before your child gets VAXELIS, read this document and be sure you understand all of the information. Keep this document, you may need to read it again. If you have questions or side effects, ask your child's healthcare provider. This information does not take the place of talking about VAXELIS with your child's healthcare provider.

What is VAXELIS?

VAXELIS is a vaccine given to protect your child from getting diphtheria, tetanus (lockjaw), pertussis (whooping cough), polio, Hib (*Haemophilus influenzae* type b), and hepatitis B.

Your child cannot get any of these diseases from VAXELIS.

VAXELIS may not completely protect your child from these diseases.

Who should not get VAXELIS?

Your child should not get VAXELIS, if your child:

- is allergic to any of the ingredients.
- had an allergic reaction to any prior shot for diphtheria, tetanus, pertussis, polio, Hib, or hepatitis B.
- had a serious reaction affecting their brain and nervous system after a whooping cough shot.
- has a brain and nerve illness that is getting worse.

Before your child gets VAXELIS, tell your healthcare provider if your child:

- had problems with any shots for these diseases.
- is taking steroids, getting treatment for cancer, or has another problem that weakens the immune system.

How is VAXELIS given?

- VAXELIS is given to children from 6 weeks through 4 years of age (up to 5th birthday).
- Your child will need 3 shots:
 - one shot at 2 months old, **and**
 - one shot at 4 months old, **and**
 - one shot at 6 months old
- If your child misses a shot of VAXELIS, your healthcare provider may suggest a catch-up schedule.
- Your child may get VAXELIS at the same time they get other vaccines.

What are the most common side effects of VAXELIS?

- pain, redness, or swelling where the shot was given
- fever (100.4°F or higher)
- crying more than usual

- eating less than usual
- fussy more than usual
- sleepy more than usual
- throwing up

There may be other side effects that are not listed. If your child has any side effects that worry you or seem to get worse, tell your child's healthcare provider right away.

You may report any side effects directly to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or <http://vaers.hhs.gov>, or contact Sanofi Pasteur Inc., at 1-800-822-2463 (1-800-VACCINE).

To learn more about VAXELIS, ask your healthcare provider. You can also find the Full Prescribing Information written for doctors at www.fda.gov/media/119465/download.

What is in VAXELIS?

- Active ingredients: inactivated bacteria of diphtheria, tetanus, pertussis, Hib, and inactivated hepatitis B and polio viruses. The bacteria and viruses in VAXELIS are not alive and do not cause disease.
- Other ingredients: aluminum salts, polysorbate 80, glutaraldehyde, formaldehyde, bovine serum albumin, neomycin, streptomycin, polymyxin B, ammonium thiocyanate, yeast protein, and water.
- VAXELIS does not have any preservatives in it.
- VAXELIS vial stopper, syringe plunger stopper, and syringe tip cap do not contain natural rubber latex.

Manufactured by: **Sanofi Pasteur Limited** Toronto Ontario Canada for: MSP Vaccine Company
Swiftwater PA 18370 USA.

Distributed by: **Merck Sharp & Dohme Corp.**, a subsidiary of **Merck & Co., Inc.** Whitehouse Station NJ
08889 USA, and by **Sanofi Pasteur Inc.** Swiftwater PA 18370 USA.

VAXELIS is a trademark of MSP Vaccine Company. The trademarks depicted herein are owned by their respective companies.

Initial Approval: 23 October 2020

R0-1020