

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Trumenba®

Meningococcal group B vaccine

[Bivalent recombinant lipoprotein (rLP2086)]

Neisseria meningitidis serogroup B rLP2086 subfamily A 60 mcg, *Neisseria meningitidis* serogroup B rLP2086 subfamily B 60 mcg per 0.5 mL, Suspension for Intramuscular Injection

Read this carefully before you/your child receives **Trumenba**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your/your child's healthcare professional about your/your child's medical condition and treatment and ask if there is any new information about **Trumenba**.

What is Trumenba used for?

- Trumenba is a vaccine to prevent invasive meningococcal disease, caused by *Neisseria meningitidis* serogroup B bacteria, for use in people aged 10 through 25 years. Invasive meningococcal group B disease (also known as meningitis B) is a serious and sometimes life-threatening bacterial infection that can result in meningitis (inflammation of the covering of the brain and spinal cord) and sepsis (blood poisoning). Meningitis B can spread from person to person through close contact (such as coughing or kissing) or lengthy contact, especially among people living in the same household.

How does Trumenba work?

Trumenba targets a protein found in over 95% of bacteria that cause meningitis B. It works by helping the body to make antibodies (the body's natural defences), which protect you or your child against this disease. These antibodies kill the bacteria that cause meningitis B. If a vaccinated person comes into contact with the bacteria that cause this disease, their body is usually ready to destroy them.

What are the ingredients in Trumenba?

Medicinal ingredients: 1 dose (0.5 mL) contains the following active substances:

- Neisseria meningitidis* serogroup B recombinant lipoprotein (rLP2086) subfamily A: 60 micrograms
- Neisseria meningitidis* serogroup B recombinant lipoprotein (rLP2086) subfamily B: 60 micrograms

Non-medicinal ingredients: aluminum phosphate, histidine, polysorbate 80, sodium chloride, water for injection

Trumenba comes in the following dosage forms:

A white suspension for injection, provided in a single-dose, pre-filled syringe.

Do not use Trumenba if:

- You or your child are allergic to the active substance or any of the other ingredients of this vaccine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you/your child receives Trumenba. Talk about any health conditions or problems you/your child may have, including if you/your child:

- Have any problems after any dose of Trumenba such as an allergic reaction or problems with breathing.

- Have any problem that may stop your blood from clotting properly.
- Have a weakened immune system, which may prevent you or your child from getting the full benefit from Trumenba, for example due to complement deficiencies or medicines that suppress the immune system (for example eculizumab).
- Are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby. Ask your healthcare professional for advice before receiving Trumenba. Your healthcare professional may still recommend that you receive Trumenba if you are at risk of meningococcal disease.

Fainting, feeling faint, or other stress-related reactions can occur as a response to any needle injection. Tell your doctor, pharmacist or nurse if you or your child have experienced this kind of reaction previously.

Trumenba has little or no influence on the ability to drive or use machines. However, some of the effects mentioned under the section “**What are possible side effects from using Trumenba?**” may temporarily affect the ability to drive or use machines.

Other warnings you should know about:

- As with any vaccine, Trumenba may not fully protect everyone who is vaccinated.

Tell your healthcare professional about all the medicines you/your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Trumenba:

- If you or your child take medicines or receive therapies that affect your immune system (such as radiation therapy, eculizumab, steroids or some types of cancer chemotherapies), you or your child may not get the full benefit of Trumenba, or may remain at increased risk for disease caused by meningococcal group B bacteria even if you develop antibodies following vaccination with Trumenba.

Trumenba can be given at the same time as any of the following vaccines: quadrivalent human papillomavirus vaccine (HPV4), meningococcal serogroups A, C, W, Y conjugate vaccine (MenACWY) and tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine adsorbed (Tdap).

When Trumenba is given at the same time as another vaccine, the vaccines must be given in different syringes and at separate injection sites.

How Trumenba is given:

Trumenba (0.5 mL) will be given to you or your child by a healthcare professional (doctor, nurse or pharmacist). It will be injected into the upper arm muscle.

It is important to follow the instructions from the healthcare professional so that you or your child receives all of the injections.

Dosing schedule (depending on the risk from disease):

Individuals 10 through 25 years

- You or your child will receive 2 injections of the vaccine. The second injection is given 6 months after the first injection.

or

- You or your child will receive 2 injections of the vaccine given at least 1 month apart and a third injection at least 4 months after the second injection.
- You or your child may be given a booster.

Overdose:

Overdose with Trumenba is unlikely as it is supplied as a single-dose pre-filled syringe.

If you think you/your child have received too much Trumenba, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to go back to your healthcare professional at the scheduled time for your/your child's next dose, ask your healthcare professional for advice.

What are possible side effects from using Trumenba?

Like all vaccines, Trumenba can cause side effects, although not everybody gets them.

These are not all the possible side effects you/your child may have when taking Trumenba. If you/your child experience any side effects not listed here, tell your healthcare professional.

When Trumenba is given to you or your child, the following side effects may occur:

Very common (these may affect more than 1 in 10 people)

- headache
- nausea
- diarrhea
- muscle pain, joint pain
- redness, swelling and pain at injection site
- chills
- fatigue (tiredness)

Common (these may affect more than 1 in 100 people)

- vomiting
- fever $\geq 38^{\circ}\text{C}$

Side effects that have been reported during marketed use include:

- allergic reactions
- fainting

If you/your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Pfizer Canada ULC cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Store in a refrigerator (2°C to 8°C).

Store syringes in the refrigerator horizontally (laying flat on the shelf).

Do not freeze. Discard if the vaccine has been frozen.

Do not use this vaccine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Keep out of reach and sight of children.

If you want more information about Trumenba:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.pfizer.ca, or by calling 1-800-463-6001 (Pfizer Medical Information).

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