

TRUMENBA®

Meningococcal group B vaccine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Trumenba.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child being given Trumenba against the benefits it is expected to have for you or your child.

If you have any concerns about this vaccination, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What TRUMENBA is used for

Trumenba is a vaccine, a type of medicine used to protect against infectious diseases.

Trumenba is used to prevent invasive meningococcal disease caused by bacteria called *Neisseria meningitidis* serogroup B.

The *Neisseria meningitidis* bacteria can cause serious and sometimes life-threatening infections such as meningitis (inflammation of the covering of the brain and spinal cord) and sepsis (blood poisoning).

Trumenba does not help to protect against meningococcal disease caused by other types of *Neisseria* bacteria.

It does not protect against meningitis and blood poisoning caused by other bacteria or viruses.

When a person is given Trumenba, the immune system (the body's natural defence system) will produce its own protection (antibodies) against disease.

Your body usually takes several weeks after vaccination to develop protection against invasive meningococcal disease.

Most people will produce enough antibodies to protect them against invasive meningococcal disease.

However, as with all vaccines, 100% protection cannot be guaranteed.

Trumenba will not give you or your child meningococcal disease.

The chance of a severe reaction from Trumenba is very small, but the risks from not being vaccinated against invasive meningococcal disease may be very serious.

Trumenba is used in adults and children aged 10 years and older.

Before you are given TRUMENBA

When you must not be given it

You should not be given Trumenba if you have an allergy to:

- any meningococcal group B vaccine or you have had an

allergic reaction to a previous dose of Trumenba

- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not give this medicine to a child under the age of 10 years.

Safety and effectiveness in children younger than 10 years have not been established.

This medicine should not be given if the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines. Tell your doctor if you or your child have or have had any of the following medical conditions:

- low blood platelet count (thrombocytopenia) or a blood clotting disorder
- if you or your child are taking anti-coagulation medicine or undergoing anti-coagulation therapy as there is a risk of

bleeding at the injection site following vaccination

- you or your child have any condition, treatment or medicines that affect the immune response to infections.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

The vaccine should not be used during pregnancy or breast-feeding unless there is a defined risk of meningococcal disease.

If there is a need to consider vaccination during pregnancy or breast-feeding, your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given Trumenba.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by Trumenba or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or nurse if you or your child has been given other vaccines.

Your doctor will advise you if you or your child need to have Trumenba at the same time as other injected vaccines.

Trumenba may be given at the same time as other vaccines as long as they are given at different places on the body and using separate syringes.

It can be given at the same time as any of the following vaccines:

- Reduced Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis and Inactivated Poliovirus Vaccine (dTTaP-IPV)
- Quadrivalent Human Papillomavirus vaccine (HPV4)
- Meningococcal Serogroups A, C, W, Y conjugate vaccine (MnACWY)
- Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap)

If you take medicines that affect your immune system (such as radiation therapy, corticosteroids or some types of cancer chemotherapies), you may not get the full benefit of Trumenba.

How TRUMENBA is given

How is it given

Your doctor or nurse will give Trumenba as an injection. The vaccine (0.5 mL) is injected into the upper arm muscle.

Trumenba must not be injected into a vein, within or between the layers of skin or just under the skin.

When is it given

You or your child will receive two injections of the vaccine; the second injection is given 6 months after the first injection.

People who are at increased risk of invasive meningococcal disease, 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.

If you miss a dose

Your doctor or nurse will inform you about the vaccination schedule to follow.

If you or your child miss a recommended dose or stop the

vaccination course, this may result in incomplete protection.

If you are given too much (overdose)

An overdose is highly unlikely, as it is given as a single-dose syringe by a doctor or nurse.

If the doses are given closer together than recommended or more doses than required are given, side effects are more likely to occur.

Immediately telephone your doctor or Poisons Information Centre (telephone Australia 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have been given too much Trumenba.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are being given TRUMENBA

Things you must do

Keep a record of you or your child's vaccinations, and update this after each injection.

Keep any follow-up visits with your doctor or clinic.

It is important for you or your child to have follow-up doses of Trumenba to make sure the vaccine has the best chance of providing protection against meningococcal disease.

Things to be careful of

Be careful driving or operating machinery.

Trumenba has no or little influence on the ability to drive and use machines however as with other vaccines it may cause you to faint or feel lightheaded. You need to take caution until you know how the vaccine has affected you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given Trumenba.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of being given Trumenba, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Do not be alarmed by the list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following:

- headache
- nausea or vomiting
- loose bowel motions (diarrhoea)
- muscle pain
- joint pain
- redness, swelling and pain at injection site
- chills
- fatigue
- fever (38°C or higher)
- fainting or feeling lightheaded

The above list includes the more common side effects of your medicine.

As with all vaccines given by injection, there is a small risk of a serious allergic reaction. This can happen soon after the injection but may occur days to weeks after vaccination.

Tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital, if you notice any of the following:

- sudden signs of allergy such as rash, itching or hives on the skin
- swelling of the, face, lips, tongue or other parts of the body
- shortness of breath, breathing or swallowing difficulties

Tell your doctor or pharmacist if you notice anything else that is making you or your child feel unwell.

Others side effects not listed above may also occur in some people.

There may also be some side effects not yet known.

After being given TRUMENBA

Storage

Trumenba is usually stored in the doctor's surgery or clinic, or at the pharmacy.

However, if you need to store Trumenba keep it in the fridge, stored between 2°C and 8°C.

The vaccine should be stored in the fridge horizontally.

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

Do not store Trumenba or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

Disposal

If your doctor tells you that you no longer require this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Trumenba is a white suspension for injection, provided in a pre-filled syringe.

Ingredients

Trumenba (0.5 mL) contains the following active ingredients:

60 mcg of Neisseria meningitidis serogroup B recombinant lipidated - factor H binding protein subfamily A

60 mcg of Neisseria meningitidis serogroup B recombinant lipidated - factor H binding protein subfamily B.

It also contains:

- polysorbate 80
- aluminium phosphate
- sodium chloride
- histidine
- water for injections.

Supplier

Trumenba is supplied in Australia by:

Pfizer Australia Pty Ltd
38-42 Wharf Road
West Ryde NSW 2114
Australia

Toll Free number: 1800 675 229

Australian registration number

AUST R 276920

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