

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I getting Trumenba?

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.

For more information, see Section [1. Why am I getting Trumenba?](#) in the full CMI.

2. What should I know before I am given Trumenba?

Do not use if you or your child have ever had an allergic reaction to any meningococcal group B vaccine or you have had an allergic reaction to a previous dose of Trumenba or any of the ingredients listed at the end of the CMI.

This medicine should not be given to a child under the age of 10 years.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Trumenba?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines or if you or your child has been given other vaccines.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Trumenba given?

- Your doctor or nurse will give Trumenba as an injection. The vaccine (0.5 mL) is injected into the upper arm muscle
- You or your child will receive two injections of the vaccine; the second injection is given 6 months after the first injection.

More instructions can be found in Section [4. How is Trumenba given?](#) in the full CMI.

5. What should I know while or after given Trumenba?

Things you should do	<ul style="list-style-type: none">• Keep a record of you or your child's vaccinations, and update this after each injection.
Driving or using machines	<ul style="list-style-type: none">• 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.
Looking after your medicine	<ul style="list-style-type: none">• Trumenba is usually stored in the doctor's surgery or clinic, or at the pharmacy

For more information, see Section [5. What should I know while or after given Trumenba?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Some of the common side effects are 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Trumenba®

Active ingredient(s): *Meningococcal group B vaccine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Trumenba. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Trumenba.**

Where to find information in this leaflet:

- [1. Why am I getting Trumenba?](#)
- [2. What should I know before I am given Trumenba?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Trumenba?](#)
- [5. What should I know while or after given Trumenba?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I getting Trumenba?

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 defense 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.

2. What should I know before I am given Trumenba?

Warnings

You should not be given Trumenba if:

- you are allergic to any meningococcal group B vaccine or you have had an allergic reaction to a previous dose of

Trumenba, or any of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can use this medicine

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 of the vaccine 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.

Check with your doctor if you:

- 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.
- You or your child have any other medical conditions or take medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Talk to your doctor if you are breastfeeding or intend to breastfeed.

The vaccine should not be used during pregnancy or breastfeeding 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.

3. What if I am taking other medicines?

Some medicines may be affected by Trumenba or may affect how well it works.

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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.

Tell your doctor or nurse if you or your child have 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 (dTaP-IPV)
- Quadrivalent Human Papillomavirus vaccine (HPV4)
- Meningococcal Serogroups A, C, W, Y conjugate vaccine (MenACWY)
- Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Trumenba.

4. How do I use Trumenba?

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 or your child is at continued risk of invasive meningococcal disease, your doctor may give you or your child an additional injection (booster dose).

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 use too much

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.

5. What should I know while or after given Trumenba?

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Trumenba affects you.

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.

Looking after your medicine

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 young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

More Common side effects

More Common side effects	What to do
<ul style="list-style-type: none">• 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	Speak to your doctor if you have any of these common side effects and they worry you.

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

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• 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	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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 or pharmacist if you notice anything else that may be making you or your child feel unwell.

Other side effects not listed here may occur in some people. There may also be some side effects not yet known.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Trumenba contains

Active ingredient (main ingredient)	60 micrograms of Neisseria meningitidis serogroup B recombinant lipidated - factor H binding protein subfamily A 60 micrograms of Neisseria meningitidis serogroup B recombinant lipidated - factor H binding protein subfamily B.
Other ingredients (inactive ingredients)	polysorbate 80 aluminium phosphate sodium chloride histidine water for injections.

Do not take this medicine if you are allergic to any of these ingredients.

What Trumenba looks like

Trumenba is homogenous white suspension in a prefilled syringe (Aust R 276920).

Who distributes Trumenba

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in November 2022.