Package leaflet: Information for the user

Trumenba suspension for injection in pre-filled syringe
Meningococcal group B vaccine
(recombinant, adsorbed)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you or your child receives this vaccine because it contains important information for you or your child

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This vaccine has been prescribed for you or your child only.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Trumenba is and what it is used for

Trumenba is a vaccine to prevent invasive meningococcal disease, caused by *Neisseria meningitidis* serogroup B, for use in people 10 years and older. This is a type of bacteria that 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).

The vaccine contains two important components from the surface of the bacteria.

The vaccine works by helping the body to make antibodies (the body's natural defences) which protect you or your child against this disease.

2. What you need to know before you or your child receives Trumenba

Trumenba should not be given:
- if you or your child are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before vaccination with Trumenba. Tell your doctor, pharmacist or nurse if you or your child:
- have a severe infection with a high fever. If this is the case, then vaccination will be postponed. The presence of a minor infection, such as a cold, should not require

postponement of the vaccination, but talk to your doctor first.
- have a bleeding problem or bruise easily.
- have a weakened immune system which may prevent you or your child from getting the full benefit from Trumenba.
- have had any problems after any dose of Trumenba such as an allergic reaction or problems with breathing.

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 have experienced this kind of reaction previously.

Other medicines and Trumenba
Tell your doctor, pharmacist or nurse if you or your child are using, have recently used or might use any other medicines or have recently received any other vaccine.

Trumenba can be given at the same time as any of the following vaccine components: tetanus, diphtheria, whooping cough (pertussis), poliovirus, papillomavirus, and meningococcal serogroups A, C, Y, W.

Administration of Trumenba with vaccines other than those mentioned above, has not been studied.

If you receive more than 1 vaccination at the same time it is important that different injection sites are used.

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.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before Trumenba is given. Your doctor may still recommend that you receive Trumenba if you are at risk of meningococcal disease.

Driving and using machines
Trumenba has no or little influence on the ability to drive and use machines.

However, some of the side effects mentioned under section 4 ‘Possible side effects’ may temporarily affect you. If this occurs, wait until the effects wear off before driving or using machines.

Trumenba contains sodium
This medicinal product contains less than 23 mg sodium per dose, i.e. essentially ‘sodium-free’.

3. How Trumenba is given

Trumenba will be given to you or your child by a doctor, pharmacist or nurse. It will be injected into the upper arm muscle.

It is important to follow the instructions from the doctor, pharmacist or nurse so that you or your child completes the course of injections.

Individuals 10 years and older

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

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.

4. Possible side effects

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

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

Very common (these may affect more than 1 in 10 people)
- Redness, swelling and pain at injection site
- Headache
- Diarrhoea
- Nausea
- Muscle pain
- Joint pain
- Chills
- Fatigue

Common (these may affect up to 1 in 10 people)
- Vomiting
- Fever ≥ 38°C

Not known (cannot be estimated from available data)
- Allergic reactions

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

United Kingdom
Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Malta
ADR Reporting. Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Trumenba

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

Store in a refrigerator (2 °C-8 °C).

Syringes should be stored in the refrigerator horizontally to minimize the re-dispersion time.

Do not freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Trumenba contains

One dose (0.5 ml) contains:

Active substances:

Neisseria meningitidis serogroup B fHbp subfamily A[1,2,3]	60 micrograms
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[1] Recombinant lipidated fHbp (factor H binding protein)
[2] Produced in *Escherichia coli* cells by recombinant DNA technology
[3] Adsorbed on aluminium phosphate (0.25 milligram aluminium per dose)

Other ingredients:

Sodium chloride, histidine, water for injections, and polysorbate 80 (E433).

What Trumenba looks like and contents of the pack

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

Pack sizes of 1, 5, and 10 pre-filled syringes with or without needles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Pfizer Europe MA EEIG
Boulevard de la Plaine 17
1050 Bruxelles
Belgium

Manufacturer responsible for batch release:
Pfizer Manufacturing Belgium N.V.
Rijksweg 12
B-2870 Puurs
Belgium

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland
Pfizer Healthcare Ireland

Malta
Vivian Corporation Ltd.

Tel: 1800 633 363 (toll free)
+44 (0)1304 616161

Tel: + 35621 344610

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Pfizer Limited
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This leaflet was last revised in 09/2018.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

The following information is intended for healthcare professionals only:

During storage, a white deposit and clear supernatant may be observed.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

Shake well prior to use to obtain a homogeneous white suspension.

Trumenba is for intramuscular use only. Do not administer intravascularly or subcutaneously.

Trumenba must not be mixed with any other vaccines in the same syringe.

When given at the same time with other vaccines Trumenba must be given at separate injection sites.

Any unused vaccine or waste material should be disposed of in accordance with local requirements.