Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Trumenba®, suspension for injection

Each dose (0.5 ml) contains:

Meningococcus B, multicomponent vaccine subfamily A[1,2,3]	60 micrograms
Meningococcus B, multicomponent vaccine subfamily B[1,2,3]	60 micrograms

[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)

For a list of inactive ingredients and allergens in the preparation: See section 2 under 'Important information about some of this medicine's ingredients' and section 6, 'Further information.'

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Trumenba® is intended for active immunization of children from the age of 10 years and older and of adults to prevent invasive meningococcal disease caused by *Neisseria meningitidis* bacteria (meningococcus) of serogroup B.

Therapeutic group: vaccine against meningococcal disease.

Neisseria meningitidis is a bacteria that can cause a serious and sometimes life-threatening infection such as meningitis (inflammation of the covering of the brain and spinal cord) and sepsis (blood poisoning).

The vaccine contains a component from the surface of the bacteria. The vaccine works by helping the body to make antibodies (part of the body's natural defense system) which protect you or your child against this disease.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You or your child are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine, listed in section 6.

Special warnings regarding use of the medicine

Before treatment with Trumenba®, tell your doctor if you or your child:

- have a severe infection with a high fever. In such case, postpone vaccination. The presence of a minor infection, such as a cold, should not require postponement of the vaccination, but consult with the doctor before vaccination.
- have a bleeding problem or bruise easily.
- have a weakened immune system that may prevent you or your child from deriving the full benefit from the vaccine.
- have had any problem in the past after vaccination with Trumenba®, such as an allergic reaction or difficulties breathing.

Fainting, feeling faint or other stress-related feelings may arise as a response to any injection. Tell your doctor or nurse if you experienced such a feeling in the past.

Children and adolescents
This medicine is not intended for children under the age of 10 years.
There is no information about the safety and efficacy of using this preparation in children under the age of 10 years.

Drug interactions
If you or your child are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Tell your doctor or nurse if you or your child have recently received any other vaccine.

Trumenba® can be given concomitantly with the following vaccines: tetanus, diphtheria, whooping cough (pertussis), poliovirus, papillomavirus and meningococcal serogroups A, C, W, Y.

Administration of Trumenba® concomitantly with vaccines other than those mentioned above has not been evaluated.

If you or your child are given more than one vaccine at the same time, it is important to give the vaccines at different injection sites on the body.

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

Pregnancy, breastfeeding, and fertility
If you or your daughter are pregnant or breastfeeding, think that you or your daughter might be pregnant or are planning to become pregnant, contact the doctor to receive advice before vaccination.
There is no information about the use of Trumenba® in pregnant women.
The doctor may still recommend administering Trumenba® if you or your daughter are at risk of meningococcal disease.

It is not known whether Trumenba® passes into mother's milk. Trumenba® should only be used during breastfeeding when the possible advantages outweigh the potential risks.

Animal studies do not indicate direct or indirect harmful effects with respect to fertility in females. Trumenba® has not been evaluated in relation to impairment of fertility in males.

Driving and using machines
Trumenba® has little or no effect on the ability to drive or operate machines.
However, some of the side effects mentioned in section 4 'Side effects' may temporarily affect you. If this occurs, wait until the affect subsides before driving or using machines.

Important information about some of this medicine's ingredients
Trumenba® contains sodium.
Trumenba® contains less than 1 mmol sodium (23 mg) per dose; that is to say, it is considered sodium-free.

3. HOW TO USE THIS MEDICINE?
Always use this preparation according to your doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by your doctor only.

The vaccine will be given to you or to your child by a doctor or nurse. The vaccine will be given by intramuscular injection in the upper arm. Follow the doctor's instructions in order to complete the full series of injections.

The customary dosages are usually:
From 10 years of age and older:

Two doses: you or your child will receive 2 doses of the vaccine. The second dose will be given 6 months after the first dose.
or
Three doses: you or your child will receive 2 doses of the vaccine, which will be given at least one month apart from each other, and a third dose, which will be given at least four months after the second dose.

You or your child may receive a booster dose.

Do not exceed the recommended dose.

Persist with the treatment as recommended by your doctor.

If you received an overdose, contact the doctor immediately or proceed to a hospital emergency room and bring the medicine package with you.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Trumenba® may cause side effects in some users. Do not be alarmed by the list of side effects; you may not experience any of them.

Very common side effects (may affect more than 1 in 10 people):
- Redness, swelling and pain at the injection site
- Headache
- Diarrhea
- Nausea
- Muscle pain
- Joint pain
- Chills
- Fatigue

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

Side effects of unknown frequency (frequency cannot be estimated from avaliable data):
- Allergic reactions

If you experience any side effect, if any side effect gets worse, or if you experience a side effect that has not been mentioned in this leaflet, consult the doctor.

You can report side effects to the Ministry of Health by following the link "Reporting Side Effects of Drug Treatment" on the Ministry of Health homepage (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C-8°C). Do not freeze. Syringes should be stored in a refrigerator horizontally.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Sodium chloride, histidine, aluminum phosphate, polysorbate 80 and water for injection.

What the medicine looks like and contents of the pack:
Trumenba® is marketed as a white suspension (0.5 ml) for injection, in a pre-filled syringe. The pack contains 1, 5 or 10 pre-filled syringes with or without a needle. Not all pack sizes may be marketed.

Registration holder and address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituah 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
164-43-35401

Revised in 07/2021 according to MOH guidelines.

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 and waste material should be disposed of in accordance with local requirements.