PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

TRUMENBA® (**Meningococcal B vaccine) Suspension for injection**

***Neisseria meningitidis* Serogroup B recombinant Lipoprotein (rLP2086; subfamily A and B; *E.coli*)**

Sugar-free

Read all of this leaflet carefully before you are given TRUMENBA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TRUMENBA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TRUMENBA is and what it is used for

TRUMENBA is a vaccine used to prevent invasive meningococcal disease, caused by *Neisseria meningitidis* serogroup B, in individuals 10 years and older.

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 are given TRUMENBA

TRUMENBA should not be administered to you

- if you are hypersensitive (allergic) to meningococcal group B or any of the other ingredients of TRUMENBA (listed in section 6)
- if you have ever had a severe allergic reaction after any previous dose of TRUMENBA or to any component of this vaccine

Warnings and precautions

Take special care with TRUMENBA

- if you or your child suffer from bleeding problems or bruise easily
- if you have a weakened immune system which may prevent you or your child from getting the full benefit from TRUMENBA
- if you have a severe illness 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 health care provider first

Fainting can occur as a response to receiving TRUMENBA. Tell your health care provider if you have experienced this kind of reaction previously.

Other medicines and TRUMENBA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

If you are taking 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 breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving this medicine.

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.

It is not always possible to predict to what extent TRUMENBA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TRUMENBA affects them.

3. How to use TRUMENBA

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself TRUMENBA. It will be given to you by a person who is qualified to do so.

The usual dose is 2 injections of the vaccine. The second injection is given 6 months after the first injection.

If you or your child is at increased risk of meningococcal disease, you will receive 2 injections given at least 1 month apart followed by a third injection at least 4 months after the second dose.

Under certain circumstances, you or your child may also be given a booster.

If you have the impression that the effect of TRUMENBA is too strong or too weak, tell your doctor or

pharmacist.

If you given more TRUMENBA than you should

Since a health care provider will administer TRUMENBA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of TRUMENBA

If you think you have missed a dose, tell your doctor. Do not receive a double dose to make up for forgotten individual doses.

Since a health care provider will administer TRUMENBA, it is unlikely that the dose will be missed.

4. Possible side effects

TRUMENBA can have side effects.

Not all side effects reported for TRUMENBA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving TRUMENBA, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to TRUMENBA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- headache

- diarrhoea
- nausea
- vomiting
- muscle pain
- joint pain
- chills
- fatigue
- redness, swelling and pain at injection site
- fever

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TRUMENBA.

5. How to store TRUMENBA

- Store all medicines out of reach of children.
- TRUMENBA should be stored in a refrigerator (2 °C - 8 °C).
- Do not freeze. Do not use if frozen.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TRUMENBA contains

- The active ingredient is meningococcal group B (bivalent rLP2086).
- Each 0,5 mL dose contains 60 µg each *Neisseria meningitidis* Serogroup B recombinant

Lipoprotein (rLP2086; subfamily A and B; *E.coli*).

- The other ingredients are aluminium phosphate, histidine, polysorbate 80, sodium chloride and water for injection.

What TRUMENBA looks like and contents of the pack

A homogeneous white suspension.

TRUMENBA 0,5 mL suspension is available in a pre-filled syringe (Type I glass) with plastic Luer Lok adapter, chlorobutyl rubber plunger stopper, and a synthetic isoprene bromobutyl rubber tip cap with a plastic rigid tip cap cover with or without a needle. The tip cap and rubber plunger of the pre-filled syringe are not made with natural rubber latex.

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

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

Tel: +27(0)11 320 6000 / 0860 734 937 (Toll-free South Africa)

This leaflet was last revised in

06 October 2020

Registration number

52/30.2/0987