APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DYNA TEICOPLANIN 200 mg (Lyophilised sterile powder for injection)

DYNA TEICOPLANIN 400 mg (Lyophilised sterile powder for injection)

DYNA TEICOPLANIN Solvent (Water for injection)

Teicoplanin

DYNA TEICOPLANIN is sugar-free.

Read all of this leaflet carefully before you are given DYNA TEICOPLANIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DYNA TEICOPLANIN 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 DYNA TEICOPLANIN is and what it is used for

DYNA TEICOPLANIN is an antibiotic prescribed by medical practitioners to both children older than 3 years and adults to treat certain microbial infections. The dosage and duration of the treatment is unique to your infection.

DYNA TEICOPLANIN is indicated in the treatment of infections of the blood, lungs, airways, heart, bone and joints, skin and soft tissues, urinary tract and bowel. DYNA TEICOPLANIN may also be used before some operations to prevent infection.

DYNA TEICOPLANIN can be used to treat antibiotic associated diarrhoea caused by *Clostridium difficile* bacteria in the gut. For this, the solution is taken by mouth.

2. What you need to know before you take/use DYNA TEICOPLANIN

DYNA TEICOPLANIN should not be administered to you:

- if you are hypersensitive (allergic) to teicoplanin, or to any of the ingredients of DYNA TEICOPLANIN (see section 6)
- if you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding)
- children younger than three years of age should not be given DYNA TEICOPLANIN as safety and efficacy have not been established in this age group
- DYNA TEICOPLANIN must not be injected into the subarachnoid space between the

two membranes surrounding the brain.

Warnings and precautions

Take special care with DYNA TEICOPLANIN:

Tell your doctor or healthcare professional before you are given this injection:

- if you are allergic to an antibiotic called vancomycin or are generally an allergic person
- if you have flushing of the upper part of your body (red man syndrome), your doctor may discontinue or reduce your treatment
- if you develop a skin rash with blisters or irritation or sores in your mouth, as your doctor will discontinue your treatment immediately
- if you have a decrease in platelet count (thrombocytopenia)
- if you have kidney problems
- if you are taking other medicines which may cause hearing problems and/or kidney problems or experience hearing loss or ear problems. You may have regular tests to check if your blood, kidneys and/or liver are working properly (see Other medicines and DYNA TEICOPLANIN)
- if you are given DYNA TEICOPLANIN for a long time, bacteria that are not affected by the antibiotic may grow more than normal - your doctor will check for this.

During treatment you may have tests to check your kidneys and/or your hearing. This is more likely:

- if your treatment will last for a long time
- if you have a kidney problem

- if you are taking or may take other medicines that may affect your nervous system, kidneys or hearing.

You should not receive DYNA TEICOPLANIN by intraventricular route (a fluid filled space in the brain), due to the risk of fits (seizures).

Other medicines and DYNA TEICOPLANIN

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

In particular, tell your doctor if you are using any of the following medicines:

- antibiotics called aminoglycosides as they must not be mixed together with DYNA TEICOPLANIN in the same injection
- amphotericin B - a medicine that treats fungal infections
- ciclosporin - a medicine that affects the immune system, used to prevent rejection of transplanted organs
- cisplatin - a medicine that treats malignant tumours
- water tablets (such as furosemide and ethacrynic acid) - also called ‘diuretics’
- colistin – an antibiotic.

DYNA TEICOPLANIN with food and drink

DYNA TEICOPLANIN is not influenced by food and drink as it is administered by injection. When administered orally for antibiotic associated diarrhoea, it is not absorbed and works locally in the gastro-intestinal tract.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before DYNA TEICOPLANIN is administered.

Do not receive DYNA TEICOPLANIN if you are pregnant, planning to become pregnant or breastfeeding your baby. The safety of DYNA TEICOPLANIN in pregnancy and breastfeeding has not yet been established.

Driving and using machines

DYNA TEICOPLANIN could have a minor influence on your ability to drive or use machines.

DYNA TEICOPLANIN can cause dizziness and you should take care before driving, operating hazardous machinery or performing hazardous tasks.
It is not always possible to predict to what extent DYNA TEICOPLANIN 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 DYNA TEICOPLANIN affects them.

3. How to use DYNA TEICOPLANIN

Do not share medicines prescribed for you with any other person. Always use DYNA TEICOPLANIN exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

DYNA TEICOPLANIN is for intravenous (into a vein) and intramuscular (into the muscle) use. Your doctor will decide on the suitable dose based on the type of infection you have. You will not be expected to give yourself DYNA TEICOPLANIN. It will be given to you by a person qualified to do so.

A dose of 200 mg DYNA TEICOPLANIN twice a day for 10 days can also be given by mouth to treat inflammation of the large intestine (gut), caused by infection of bacteria called *Clostridium difficile*.

Your doctor will tell you how long your treatment with DYNA TEICOPLANIN will last.
If you have the impression that the effect of DYNA TEICOPLANIN is too strong or too weak, tell your doctor or pharmacist.

If you receive more DYNA TEICOPLANIN than you should

Since a healthcare professional will administer DYNA TEICOPLANIN, he/she will control the dosage. However, in the event of an overdosage your doctor will manage the overdose.

If you missed a dose DYNA TEICOPLANIN

Since a healthcare professional will administer this medicine, it is unlikely that he/she will miss a dose.

If you stop using DYNA TEICOPLANIN

It is important that you continue the course of treatment even if you begin to feel better after a few days.

4. Possible side effects

DYNA TEICOPLANIN can have side effects.

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

If any of the following happens, stop using DYNA TEICOPLANIN and 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
- rash or itching
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- flushing of the upper body
- rash on the face, neck and upper torso (a condition called “red man syndrome”)
- blistering of the skin, mouth, eyes or genitals - these may be signs of something called ‘toxic epidermal necrolysis’ or ‘Stevens-Johnson syndrome’.

- DRESS syndrome (medicine reaction with eosinophilia and systemic symptoms). DRESS appears initially with flu-like symptoms and rash on the face, followed by extended rash with a high temperature. Abnormal blood test results include an increase in liver enzymes and a type of white blood cells (eosinophilia) as well as enlarged lymph nodes.
- loss of hearing
- difficulty in breathing or wheezing (bronchospasm)
- getting more infections than usual
- seizures (fits)
- kidney problems or changes in the way your kidneys work (shown in tests) such as raised blood levels of creatinine or symptoms like a reduced amount of urine, swelling and fatigue
- swelling and clotting in a vein near the injection site (thrombophlebitis)
- lack of white blood cells - the signs may include: fever, severe chills, sore throat or mouth ulcers (agranulocytosis)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- skin rashes or other skin conditions
- pain or abscess at the injection site
- fever.

Less frequent side effects:

- abnormal blood test results including: a high level of disease-fighting white blood cells known as eosinophils in the blood, deficiency of platelets in the blood (this causes bleeding into the tissues, bruising, and slow blood clotting after injury), getting more infections than usual (this could be due to a decrease in your blood cell count
- headache, dizziness
- pain, swelling and redness on the skin (this could be as a result of a condition called phlebitis)
- diarrhoea, vomiting, nausea
- general pain, chills, rigors (a sudden feeling of cold with shivering accompanied by a rise in temperature, often with excessive sweating, especially at the onset or height of a fever).

The following side effects have been reported but the frequency for them to occur is not known:

- ringing in the ears, spinning sensation
- raised blood levels of liver enzymes (shown in test to monitor your liver)
- hives (itchy, raised, red or skin-coloured welts on the skin's surface).

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, pharmacist or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8.

An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

By reporting side effects, you can help provide more information on the safety of DYNA TEICOPLANIN.

5. How to store DYNA TEICOPLANIN

- Store all medicines out of reach of children.
- Store at or below 25 °C. Protect from moisture.
- After reconstitution, the solution should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would not be longer than 24 hours stored at 2 °C – 8 °C, unless reconstitution/ dilution has taken place under controlled and validated aseptic conditions.
- Do not use after the expiry date stated on the carton.
- 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 DYNA TEICOPLANIN contains

The active ingredient is teicoplanin.

The other ingredients are

sodium chloride and water for injection

What DYNA TEICOPLANIN looks like and contents of the pack

DYNA TEICOPLANIN 200 mg is a white-yellow lyophilised (freeze-dried) powder.

DYNA TEICOPLANIN 400 mg is a white-yellow lyophilised (freeze-dried) powder.

DYNA TEICOPLANIN SOLVENT is a clear, colourless, odourless liquid.

When DYNA TEICOPLANIN is reconstituted, it is a clear, yellowish solution.

DYNA TEICOPLANIN 200 mg: 20 ml clear, colourless, Type I glass vial with grey bromobutyl rubber closure and an aluminium secure cap with a blue plastic removable cover.

DYNA TEICOPLANIN 400 mg: 20 ml clear, colourless, Type I glass vial with grey bromobutyl rubber closure and an aluminium secure cap with a red plastic removable cover.

DYNA TEICOPLANIN SOLVENT: 5 ml clear, colourless, Type I glass ampoules.

One vial and one ampoule are presented in an outer carton, for single use only.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

This leaflet was last revised in

13 April 2023

www.pharmadynamics.co.za

Registration number

DYNA TEICOPLANIN 200 mg: A43/20.1.1/0573

DYNA TEICOPLANIN 400 mg: A43/20.1.1/0575

DYNA TEICOPLANIN SOLVENT: A43/32.4/0574

NAMIBIA

DYNA TEICOPLANIN 200 mg: 15/20.1.1/0167

DYNA TEICOPLANIN 400 mg: 15/20.1.1/0166

DYNA TEICOPLANIN SOLVENT: 16/34/0028