APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you are given TEGORID IV

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **TEGORID IV** 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.

SCHEDULING STATUS

TEGORID IV 200 & TEGORID IV 400 Injection S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

TEGORID IV 200 & TEGORID IV 400 Injection

1. WHAT TEGORID IV CONTAINS

The active substance is lyophilised teicoplanin 200 mg and 400 mg respectively.

The other ingredient is sodium chloride.

2. WHAT TEGORID IV IS USED FOR

Teicoplanin is a bactericidal, glycopeptide antibiotic. **TEGORID IV** is used to treat a variety of potentially serious infections caused by susceptible bacteria.

3. BEFORE YOU ARE ADMINISTERED TEGORID IV

You should not be administered TEGORID IV

- if you are hypersensitive to or have had an allergic reaction with teicoplanin or any of the ingredients of **TEGORID IV**
- if you are pregnant or breastfeeding
- it must not be given to children under 3 years of age

Take special care with TEGORID IV

- your doctor will monitor you carefully if you have restricted kidney function
- if you are receiving **TEGORID IV** for a long period, your doctor will do blood, liver and kidney function tests.

Pregnancy and breast-feeding

You must not be given **TEGORID IV** if you are pregnant or breast-feeding.

If you are pregnant or breast-feeding your baby while receiving **TEGORID IV**, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery.

TEGORID IV may cause dizziness in some people. If this happens to you do not drive, use machines, or perform other tasks that need full attention.

Taking other medicines with TEGORID IV

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **TEGORID IV** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Especially check with your doctor if you are taking any of the following:

- Medicines for infections (such as the aminoglycoside antibiotics – including gentamycin, streptomycin, neomycin, kanamycin, amikacin or tobramycin) or other antibiotics (such as cephaloridine or colistin)
- Ciclosporin – used in transplant surgery and in painful joint and skin diseases.
- Cisplatin – used for some cancers
- Water tablets (diuretics) such as furosemide, ethacrynic acid

4. HOW TO RECEIVE TEGORID IV

You will be given **TEGORID IV** by a healthcare professional. It will be administered in a drip or injected into a muscle. Your doctor will decide the dose based on the type and severity of infection.

If you have more TEGORID IV than you should

Since a healthcare professional will administer **TEGORID IV**, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

If you miss a dose of TEGORID IV

Your doctor or healthcare professional will have instructions about when to give **TEGORID IV**.

5. POSSIBLE SIDE-EFFECTS

TEGORID IV can have side-effects.

Not all side-effects reported for **TEGORID IV** are included in this leaflet. Should your general health worsen while receiving **TEGORID IV**, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following serious side-effects happen, 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 **TEGORID IV**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if any of the following serious side-effects occur:

- Blistering of the skin, mouth, eyes or genitals. This may be something called “Stevens-Johnson syndrome” or “toxic epidermal necrolysis”.
- Epileptic fits.
- Yellowing of the skin and eyes, also called jaundice.

Tell your doctor or nurse if you have any of the following side-effects:

- You bruise more easily and get more infections than usual. This could be because of a blood problem (called “leucopenia”).
- Reactions at the site of the injection including reddening of the skin, pain or swelling.
- Feeling or being sick (vomiting), diarrhoea.
- Dizziness or headache.
- Breathing problems.

- Mild hearing loss, ringing in the ears or feeling dizzy.
- Infection.

Other side-effects include:

- Blood and kidney problems or changes in the way your kidneys work.

  These will show up in the results of blood tests.

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

6. STORING AND DISPOSING OF TEGORID IV

Lyophilised powder: Store at or below 25 °C and protect from moisture. Do not remove from the carton until required for use.

Reconstituted solution: Chemical and physical in-use stability has been demonstrated for 24 hours at 2 to 8 ºC.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 ºC, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Protect from freezing.

This product is for single use only.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

7. PRESENTATION OF TEGORID IV

Pack of 1 x 10 ml clear glass vial containing 200 mg of lyophilised teicoplanin substance.

Pack of 1 x 10 ml clear glass vial containing 400 mg of lyophilised teicoplanin substance.

8. IDENTIFICATION OF TEGORID IV

Vial: White or slightly brown lyophilised powder.

TEGORID IV is packed in a 10 ml type II clear glass vial with a grey chlorobutyl rubber stopper and aluminium flip-off cap with a blue (for the **TEGORID IV 200**) and green (for the **TEGORID IV 400**) polypropylene cover.

Reconstituted solution: Clear, transparent and slightly brown solution.

9. REGISTRATION NUMBERS

TEGORID IV 200: 45/20.1.1/0100

TEGORID IV 400: 45/20.1.1/0101

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

Austell Pharmaceuticals (Pty) Ltd.

1 Sherborne Road

Parktown

Johannesburg, 2193

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