PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4 (powder) and S1 (solvent)

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

TEICOWIN® 400 powder for solution for injection/infusion or oral solution

TEICOWIN® 200 powder for solution for injection/infusion or oral solution

TEICOWIN® SOLVENT water for injection.

Read all of this leaflet carefully before you are given TEICOWIN.

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

The active substance of TEICOWIN 200 and TEICOWIN 400 is teicoplanin. Each vial contains either 200 mg or 400 mg teicoplanin as teicoplanin sodium.

Sugar free.

Each ampoule of TEICOWIN SOLVENT contains 3 mL water for injection.

TEICOWIN 200 or 400 is a freeze-dried powder and it is diluted with TEICOWIN SOLVENT before use to form a solution for injection or infusion. TEICOWIN is sometimes administered as an oral solution.

WHAT TEICOWIN IS USED FOR

TEICOWIN is an antibiotic and is used to treat potentially serious infections caused by certain types of bacteria known as Gram-positive organisms.

These include infections of:

- the heart – sometimes called endocarditis
- the blood, when caused by any of the conditions listed here
- the bones and joints
- the respiratory tract, e.g. the lung
- the skin and underneath the skin (sometimes called soft tissue)
- the urinary tract (kidneys and bladder)
- the abdominal wall (peritonitis) associated with continuous ambulatory peritoneal dialysis (CAPD). CAPD is done to remove wastes, chemicals, and extra fluid from your body.

TEICOWIN may be used to prevent infection caused by Gram-positive bacteria in patients undergoing orthopaedic surgery (involving bones or joints) and vascular (involving veins) surgery who are at risk of Gram-positive infection.

TEICOWIN can be used to treat some infections caused by *Clostridium difficile* bacteria in the gut. For this, the solution is taken by mouth.

BEFORE YOU ARE GIVEN TEICOWIN

You should not be given TEICOWIN if

- you are hypersensitive (allergic) to TEICOWIN
- you are pregnant
- you are breastfeeding
- you have severe renal failure, unless your blood levels can be monitored closely.

TEICOWIN should not be given to children under 3 years of age.

TEICOWIN must not be injected into the subarachnoid space between the two membranes surrounding the brain.

Take special care with TEICOWIN

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

- you are allergic to an antibiotic called vancomycin. You may also experience an allergic reaction to TEICOWIN, which can be very serious.
- you have kidney problems
- you have a decrease in platelet count (thrombocytopenia)
- you are taking other medicines which may cause hearing problems and/or kidney problems (see Using other medicines with TEICOWIN).

You may require regular tests during treatment to check your blood, hearing, kidneys and/or liver. Testing is more likely if:

- your treatment will last for a long time
- you have a kidney problem
- you are taking or may take other medicines that may affect your nervous system, kidneys or hearing.

If you experience any of the following after you are given TEICOWIN, tell your doctor or healthcare provider immediately:

- You experience any symptoms of an allergic reaction after receiving TEICOWIN injection, e.g. chills, difficulty breathing, swelling of the lips or throat. These may be symptoms of a serious

allergic reaction and may require immediate treatment and discontinuation of TEICOWIN treatment.

- You experience any progressive skin rash with blisters of the skin or mucous membranes. These symptoms could be life-threatening and require immediate action.
- You have a flushing of your upper body (red man syndrome), which may include symptoms such as itching, swelling or difficulty breathing (see POSSIBLE SIDE EFFECTS). Stopping or slowing the rate of the infusion may improve these symptoms.
- You notice bruising or bleeding into the skin or from the gums or the nose. These may be signs of a decrease in platelet count and may require blood tests.

In people who are given TEICOWIN for a long time, bacteria that are not affected by the antibiotic may grow more than normal – your doctor will check for this.

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

Receiving TEICOWIN with food and drink

TEICOWIN 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 gastrointestinal tract.

Pregnancy and breastfeeding

TEICOWIN should not be used during pregnancy or if you are breastfeeding as safety has not been established (see BEFORE YOU ARE GIVEN TEICOWIN).
If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice, before you receive TEICOWIN.

Driving and using machinery

TEICOWIN can cause dizziness and headache (see POSSIBLE SIDE EFFECTS) which may affect your ability to drive or use machines. If you are experiencing these side effects, you should not drive or use machines.

Using other medicines with TEICOWIN

Always tell your healthcare professional if you are taking any other medicine (including complementary or traditional medicine).

Before you receive TEICOWIN, tell your doctor or healthcare professional if you are taking or have recently taken any medicines, which may cause hearing problems and/or kidney problems, such as:

- aminoglycosides, such as gentamicin (an antibiotic), used to treat certain infections. TEICOWIN and aminoglycosides should not be mixed in the same solution.
- amphotericin B – a medicine that treats fungal infections
- ciclosporin – a medicine that affects the immune system
- furosemide – water tablets (also called diuretics), which may cause hearing problems and/or kidney problems (see Take special care with TEICOWIN).

HOW TO RECEIVE TEICOWIN

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

You will not be expected to give yourself TEICOWIN. It will be given to you by a person qualified to do so, as it needs to be given as an injection into a muscle or a vein, or as an infusion through a drip into a vein.

Your doctor will have prescribed the dose of TEICOWIN which is correct for you as well as the length of your treatment, depending on the type and severity of infection you may have and your response to the treatment. Your progress will be monitored during the treatment.
If you have the impression that the effect of TEICOWIN is too strong or too weak, tell your doctor or healthcare provider.

Moderate infection: The usual adult dose of TEICOWIN is 400 mg on the first day of treatment, followed by 200 mg once daily.
Severe infection: The usual adult dose of TEICOWIN is 400 mg every 12 hours for the first 3 doses, followed by 400 mg once daily. For some severe infections, you will receive higher doses for at least 3 weeks of treatment.
However, if you suffer from kidney problems, you may be given a lower dose of TEICOWIN from the fourth day of treatment.
The dose of TEICOWIN given to children will be calculated according to the body mass of the child.

A single dose of 400 mg TEICOWIN may also be used for the prevention of infections prior to surgery.

A dose of 200 mg TEICOWIN 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*.

You should not receive TEICOWIN for more than 4 months.

If you receive more TEICOWIN than you should

Since a healthcare professional will administer TEICOWIN, he/she will control the dosage. However, if you think you have been given too much TEICOWIN or if you are agitated, talk to your doctor or healthcare provider straight away. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of TEICOWIN

Since your healthcare professional will have instructions on when to give TEICOWIN, it is most unlikely that you will not be given the dose as it has been prescribed, however if you do think you have missed a dose, tell your doctor or healthcare professional.

POSSIBLE SIDE EFFECTS

TEICOWIN can have side effects.

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

Frequency unknown:

- Sudden life-threatening allergic reaction. The signs may include difficulty in breathing or wheezing (bronchospasm), swelling (e.g. of the face and lips or tongue), rash, itching, fever, chills.
- 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.

Less frequent:

- Blistering of the skin, mouth, eyes or genitals – these may be signs of a side effect called toxic epidermal necrolysis or Stevens-Johnson syndrome.

- Flushing of the upper body (red man syndrome).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TEICOWIN. 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:

Less frequent:

- fits (seizures)
- lack of white blood cells; the signs may include fever, severe chills, sore throat or mouth ulcers (agranulocytosis).

Frequency unknown:

- swelling and clotting in a vein near the injection site
- 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.

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

Tell your doctor or healthcare professional if you notice any of the following:

Less frequent:

- decrease in platelet count
- getting more infections than usual; this could be due to a decrease in your blood cell count
- feeling or being sick (vomiting), diarrhoea or other stomach and intestine problems
- feeling dizzy or headache.

Frequency unknown:

- raised blood levels of liver enzymes (shown in test to monitor your liver)
- problems where the injection was given – such as reddening of the skin, pain or swelling

- infection (abscess) at the injection site.

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

Not all side effects reported for TEICOWIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TEICOWIN, please consult your doctor, pharmacist or other healthcare professional for advice.

STORING AND DISPOSING OF TEICOWIN

Vials of TEICOWIN must be stored at or below 25 °C.

Reconstituted vials of TEICOWIN should be used immediately; may be retained for 24 hours if stored at 2 to 8 °C.

This product is for single use only. The unused portion should be discarded in accordance with the local requirements.

Store all medicine out of the reach of children.

Do not use this medicine after the expiry date shown on the label.

Return all unused medicine to your pharmacist.

PRESENTATION OF TEICOWIN

TEICOWIN 200: 1 or 2 printed carton/s, each containing a 10 mL labelled TEICOWIN 200 vial together with a labelled TEICOWIN SOLVENT ampoule and a leaflet.

TEICOWIN 400: 1 printed carton containing a 20 mL labelled TEICOWIN 400 vial together with a labelled TEICOWIN SOLVENT ampoule and a leaflet.

IDENTIFICATION OF TEICOWIN

TEICOWIN 200: A 10 mL clear glass vial with a light grey rubber stopper and a yellow flip-off top aluminium cap; containing a spongy, ivory-coloured, homogeneous mass.

TEICOWIN 400: A 20 mL clear, glass vial with a light grey rubber stopper and a green flip-off top aluminium cap; containing a spongy, ivory-coloured, homogeneous mass.

TEICOWIN SOLVENT: A clear glass ampoule, containing 3 mL of clear, colourless, odourless liquid.

Reconstituted product: Clear, yellowish solution.

REGISTRATION NUMBERS

TEICOWIN 200: 41/20.1.1/0947

TEICOWIN 400: 41/20.1.1/0948

TEICOWIN SOLVENT: 41/34/1134

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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