

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Teicoplanina Combino 200 mg powder and solvent for solution for injection Teicoplanin**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Teicoplanina Combino 200 mg powder and solvent for solution for injection is and what it is used for
2. What you need to know before you use Teicoplanina Combino 200 mg powder and solvent for solution for injection
3. How to use Teicoplanina Combino 200 mg powder and solvent for solution for injection
4. Possible side effects
5. How to store Teicoplanina Combino 200 mg powder and solvent for solution for injection
6. Contents of the pack and other information

#### **1. WHAT Teicoplanina Combino 200 mg powder and solvent for solution for injection IS AND WHAT IT IS USED FOR**

Teicoplanina Combino 200 mg powder and solvent for solution for injection contains a medicine called teicoplanin. This belongs to a group of medicines called antibiotics. It works by killing the bacteria that cause infections in your body.

Teicoplanina Combino 200 mg powder and solvent for solution for injection is used to treat infections which cannot be treated with other antibiotics. This includes infections of the:

- Skin and underneath the skin, including muscle - sometimes called 'soft tissue'
- Urinary tract - including your kidneys or bladder
- Lungs - which affect your breathing
- Joints and bones - including your hips or knees
- Blood - sometimes called 'septicaemia'
- Heart - sometimes called 'endocarditis'
- Stomach or gut - sometimes called 'peritonitis'. This may happen if you have kidney problems and have regular home dialysis

It can also be used before some operations, to stop an infection happening.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE Teicoplanina Combino 200 mg powder and solvent for solution for injection**

##### **Do not use Teicoplanina Combino 200 mg powder and solvent for solution for injection**

- if you are allergic to teicoplanin or any of the other ingredients of this medicine (listed in section 6).

##### **Take special care with Teicoplanina Combino 200 mg powder and solvent for solution for injection**

Check with your doctor or nurse before having this medicine if:

- You have kidney problems
- You are allergic to the antibiotic called vancomycin

### **Using other medicines**

Please tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Teicoplanina Combino 200 mg powder and solvent for solution for injection can affect the way some other medicines work. Also some medicines can affect the way Teicoplanina Combino 200 mg powder and solvent for solution for injection works.

In particular, check with your doctor if you are taking any of the following:

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

### **Tests**

Your doctor may want to carry out blood tests to check on the amount of medicine in your blood. Your doctor may also do tests of your liver, kidney or hearing during treatment with Teicoplanina Combino 200 mg powder and solvent for solution for injection.

### **Pregnancy and breast-feeding**

Talk to your doctor or nurse before you are given Teicoplanina Combino 200 mg powder and solvent for solution for injection if you are pregnant, might become pregnant or are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

### **Driving and using machines**

You may have headaches or feel dizzy. If this happens, do not drive or use any machinery.

### **Important information about some of the ingredients of Teicoplanina Combino 200 mg powder and solvent for solution for injection**

Teicoplanina Combino 200 mg powder and solvent for solution for injection contains 5.5 mg of sodium in each 200 mg dose and is essentially 'sodium free'.

## **2. HOW TO USE Teicoplanina Combino 200 mg powder and solvent for solution for injection**

### **How Teicoplanina Combino 200 mg powder and solvent for solution for injection is given**

Your medicine will normally be given to you by a doctor or nurse

It will be given by injection into a vein or muscle

It can also be given as an infusion through a drip into a vein

### **How much Teicoplanina Combino 200 mg powder and solvent for solution for injection is given**

Your doctor will decide on how much Teicoplanina Combino 200 mg powder and solvent for solution for injection to give you

The dose will depend on the type of infection and any other illnesses you may have

You may be given a different dose depending on your weight

The length of your treatment will depend on your infection

If you have any kidney problems you may be given a lower dose of Teicoplanina Combino 200 mg powder and solvent for solution for injection.

The usual dose is:

*Adults (18 years and over)*

Moderate infection:

400mg on the first day

200mg once a day on the following days

Severe infection

400mg every 12 hours for the first 3 doses

400mg once a day on the following days

To stop infections happening:

Single dose of 400mg before the operation

Peritoneal Dialysis:

400 mg into your vein on the first day, followed by:

Week one: 20mg per litre in each dialysis bag

Week two: 20mg per litre in every other dialysis bag

Week three: 20mg per litre in the overnight dwell bag

**Children (2 months and over)**

Moderate infection:

10mg for every kilogram of body weight

This is given every twelve hours for the first three doses

Followed by 6mg for every kilogram of body weight, once a day

Severe infection or increased risk of infection:

10mg for every kilogram of body weight

This is given every twelve hours for the first three doses

Followed by 10mg for every kilogram of body weight, once a day

To stop infection:

Single dose of 400mg before the operation

Babies (in the first month after birth)

The usual dose of Teicoplanina Combino 200 mg powder and solvent for solution for injection is 16mg for every kilogram of body weight

Followed by 8mg for every kilogram of body weight each day

**If you have more Teicoplanina Combino 200 mg powder and solvent for solution for injection than you should**

It is unlikely that your doctor or nurse will give you too much medicine.

Teicoplanina Combino 200 mg powder and solvent for solution for injection is not usually given for more than 4 months. Your doctor and nurse will be checking your progress, and checking the medicine that you are given. Ask them if you are not sure why you are getting a dose of medicine.

**If you miss a dose of Teicoplanina Combino 200 mg powder and solvent for solution for injection**

Your doctor or nurse will have instructions about when to give you your medicine. It is unlikely that you will not be given the medicine as it has been prescribed. If you think that you may have missed a dose, then talk to your doctor or nurse.

**If you stop having Teicoplanina Combino 200 mg powder and solvent for solution for injection**

It is important that the course of treatment your doctor has prescribed is finished. Do not stop having Teicoplanina Combino 200 mg powder and solvent for solution for injection just because you feel better.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Teicoplanina Combino 200 mg powder and solvent for solution for injection can cause side effects, although not everybody gets them. These side effects are usually mild and last for a short time.

Tell your doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

- If you have an allergic reaction. The signs may include: rash, itching, fever, difficulty in breathing or wheezing, chills, swelling
- Blistering of the skin, mouth, eyes or genitals. This may be something called 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'
- Epileptic fits after the use of teicoplanin directly into the brain (intraventricular)

Tell your doctor or nurse if any of the following side effects get serious or lasts longer than a few days:

- 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
- Mild hearing loss, ringing in the ears or feeling dizzy (vertigo)
- Flushing of the upper body
- Infection

Other side effects include:

- Blood and kidney problems or changes in the way your kidney works. These would show up in the results of blood tests

If any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet, talk to your doctor or nurse.

## **5. HOW TO STORE Teicoplanina Combino 200 mg powder and solvent for solution for injection**

Keep out of the reach and sight of children.

Do not store above 30°C. Keep the container in the original package.

Do not use Teicoplanina Combino 200 mg powder and solvent for solution for injection after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

## **6. FURTHER INFORMATION**

### **What Teicoplanina Combino 200 mg powder and solvent for solution for injection contains**

- The active substance is teicoplanin. Each vial contains 200 mg of teicoplanin.
- The other ingredients are sodium chloride and, if necessary, sodium hydroxide for pH adjustment.

### **What Teicoplanina Combino 200 mg powder and solvent for solution for injection looks like and contents of the pack**

White or yellowish lyophilised porous pill.

Each pack contains one vial of Teicoplanina Combino 200 mg powder and one ampoule of water for injections.

Teicoplanina Combino 200 mg powder and solvent for solution for injection powder will be mixed with the water for injections to make a solution which is ready for use as an injection or an infusion (a drip).

**Marketing Authorisation Holder**

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**This leaflet was last approved in {MM/YYYY}**