PATIENT INFORMATION LEAFLET

TEİKOPOL 200 mg Powder and Solvent for Solution for I.M./I.V. Injection

For intravenous or intramuscular injection.

Sterile

- ***Active Substance:*** Each vial contains 200 mg teicoplanin.
- ***Excipients:*** Sodium chloride, water for injection and sodium hydroxide or hydrochloric acid as pH adjuster.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION 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.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

In this leaflet:

headlines are included.

1. What TEİKOPOL is and what it is used for

- TEİKOPOL contains an active substance called teicoplanin in dry powder form.
- TEİKOPOL is an antibiotic used for the treatment of infections caused by bacteria. These infections may occur in your joints, blood or bones. TEİKOPOL is given by injection into a vein or muscle.
- 1 vial for injection containing the active substance in dry powder form and a 3 ml ampoule containing water for injection are presented in the same package.

Each solvent ampoule contains 3 ml water for injection. Each vial of TEİKOPOL 200 mg Powder and Solvent for Solution for I.M./I.V. Injection contains 24 mg sodium chloride. Two dosage forms are available: TEİKOPOL 200 mg Powder and Solvent for Solution for I.M./I.V. Injection and TEİKOPOL 400 mg Powder and Solvent for Solution for I.M./I.V.

Injection.

- TEİKOPOL is used for the treatment of infections which cannot be treated with other antibiotics or in patients allergic to penicillin and cephalosporin group antibiotics. These infections may develop in following parts of your body:
- The skin and underneath the skin including muscles: Sometimes called “soft tissue”. Infections of these tissues.
- Urinary tract: Infections of organs including the kidney and the bladder.
- Lungs: Respiratory tract infections.
- Joint and bones: Including infections of your hip knee joints and bones
- Blood: Septicemia caused by bacteria passing into blood.
- Heart: Inflammation of the inner membrane or valves of the heart, called endocarditis.
- Stomach or intestines: The disease is called peritonitis. This can happen if you have kidney problems and are regularly dialyzed.

It is also used to prevent infection before surgery (e.g. dental and orthopedic surgery).

It is used to treat infections of patients allergic to penicillin or cephalosporin.

It can be used orally in the treatment of antibiotic-induced diarrhea caused by a bacterium called *Clostridium difficile*.

2. What you need to know before you use TEİKOPOL

DO NOT USE TEİKOPOL under the following circumstances

If:

- You are allergic to teicoplanin or any of the other ingredients of TEİKOPOL.

Signs of allergy: Rash, difficulty in breathing or swallowing due to swelling of the lips, face and tongue.

USE TEİKOPOL with CAUTION

If:

- You have kidney problems
- You are allergic to an antibiotic called ‘vancomycin’
- You are using or recently used to take other medicines which may cause hearing problems and/or kidney problems (aminoglycoside, colistin, amphotericin B, cyclosporin, cisplatin, furosemide and ethacrynic acid)
- You get a new infection while you are treated for the existing infection

If these warnings apply or applied to you, please consult your physician.

Using TEİKOPOL with food and beverages

TEİKOPOL is given by injection into a vein or muscle. However, it can be used orally in the treatment of antibiotic-induced diarrhea caused by a bacterium called *Clostridium difficile*.

Pregnancy

Please consult your physician or pharmacist before taking the drug.
You should not use TEİKOPOL if you are pregnant. Use TEİKOPOL under strict supervision of a doctor.

If you realize that you are pregnant during your treatment, immediately consult your physician or pharmacist.

Lactation
Please consult your physician or pharmacist before taking the drug.

You should not use TEİKOPOL if you are breastfeeding.
Use TEİKOPOL under strict supervision of a doctor.

Ability to drive and use machines
TEİKOPOL may cause dizziness and headache. Your ability to drive and use machines may be negatively affected. If this happens, you should not drive or use machines.

Important information regarding some of the excipients contained in TEİKOPOL
TEİKOPOL does not contain any excipients that require special precaution.
This medicinal product contains less than 1 mmol (23 mg) sodium per ml, i.e. it is essentially "sodium free".

Use in combination with other drugs
Tell your doctor if you are taking the following medicines:

- Medicines used to treat infections: Aminoglycoside antibiotics (including gentamicin, streptomycin, neomycin, kanamycin, amikacin, tobramycin) and other antibiotics (cephaloridine or colistin)
- Medicines for fungal infections (amphotericin B)
- Cyclosporine - in organ transplant surgery and painful joint and skin diseases
- Cisplatin - used in some types of cancer
- Diuretics (furosemide, ethacrynic acid)

Your doctor may ask you for regular blood tests to measure the amount of medication in your blood.

During your treatment with TEİKOPOL, your doctor may ask for liver, kidney and hearing tests.

If you are currently taking or recently took any prescribed or over-the-counter drugs, please inform your physician or pharmacist.

3. How to use TEİKOPOL
Instructions regarding correct use and dosage/administration frequency:
Your doctor will determine the dosage of your drug depending on your illness and will apply administer it to you.

Method of administration:

It will be given by injection into a vein or muscle.
Intravenous doses may be administered by rapid injection within 3-5 minutes or by slow infusion within 30 minutes.

Different doses may be required depending on your weight. The duration of treatment will vary depending on the infection.

Moderate infections:
For adults aged 18 and over, the initial dose of 400 mg is usually administered on the first day. The maintenance dose may be determined as 200 mg daily.

Severe infections:
The first three doses are 400 mg every 12 hours.
The maintenance dose is 400 mg daily.

To prevent infection:
Single dose of 400 mg before surgery.

Peritoneal dialysis:
Following the starting dose of 400 mg administered in the first day into a vein:
1st week: 20 mg/l dose in each dialysis bag
2nd week: 20 mg/l dose in one in two dialysis bag
3rd week: 20 mg/l for the dialysis bag that is kept in administration during the night

Children (2 months and older)
Moderate infections:
• For the first three administration, a dose of 10 mg/kg is given in every 12 hours.
• The maintenance dose is 6 mg/kg given once a day.

In severe infections or high risk of infection:
• For the first three administration, a dose of 10 mg/kg is given in every 12 hours.
• The maintenance dose is 10 mg/kg given once a day.

To prevent infection:
• 400 mg dose is given once before the surgery.

Infants (within one month following birth)
• 16 mg/kg on the first day, followed by 8 mg/kg given once a day.

Various age groups:
Use in children:
Your doctor will determine the dose of the drug and apply it to your child depending on your child's disease, age and other diseases.

Special cases:

If you have kidney problems, your doctor will administer the lowest dose of TEİKOPOL.
If you are under the impression that the effect TEİKOPOL is too strong or weak, consult your physician or pharmacist.

If you have taken more TEİKOPOL than you should have:
As TEİKOPOL will be used under the supervision of a doctor, necessary measures will be taken to prevent such a situation. If this is the case, the necessary treatment will be performed in the clinic.

TEİKOPOL should not be given for more than 4 months. Your doctor or nurse will check on the development of the disease and the treatment you are given.

If you have used TEİKOPOL more than you should have or more than prescribed, consult a physician or a pharmacist.

If you forget to take TEİKOPOL:
As TEİKOPOL will be used under the supervision of a doctor and the administration will be performed by qualified healthcare personnel, it is unlikely that it is forgotten to be administered.

Do not double-dose to make up for forgotten doses.

Possible effects once TEİKOPOL treatment is concluded:
As TEİKOPOL will be administered under strict supervision of a doctor, he/she will decide to stop the treatment. However, if you stop the treatment without the approval of your doctor, your complaints about the body system where the infection occurred may reappear and your general health condition may be impaired.

4. Possible side effects
Like all medicines, TEİKOPOL may cause side effects in patients sensitive to its ingredients.

If any of the following reactions happen, stop taking TEİKOPOL and tell your doctor immediately or contact the casualty department at your nearest hospital:

- Allergic reaction: Rash, itching, fever, difficulty in breathing or wheezing, chills, swelling
- Blistering of the skin, mouth, eyes or genitals. these may be signs of something called “Stevens-Johnson syndrome” or “toxic epidermal necrolysis”.
- Epileptic fits following direct administration into the brain (intraventricular)

These are all very serious side effects.
If you experience one of these side effects, it means that you are severely allergic to TEİKOPOL. You may need urgent medical attention or to be hospitalized.

If you notice any of the following side effects, tell your doctor immediately or contact the nearest emergency room:

- Getting more infections than usual. This could be signs of leukopenia and neutropenia (a decrease in your white blood cell count).
- Unusual bruising or tendency to bleed. This may be a sign of thrombocytopenia (a decrease in blood platelet count)
- Fever, sore throat, mouth ulcers and bleeding gums. This may be signs of a decrease in your white blood cell count called granulocyte (agranulocytosis).
- Pain, reddening or swelling in the site of injection.
- Nausea, vomiting, diarrhea
- Dizziness, vertigo and headache
- Redness in your upper body
- Mild hearing loss, ringing in the ears or dizziness
- Infection, fever, chills
- Inflammation of the vein (thrombophlebitis) manifested by redness, swelling of the skin and pain in that area
- Difficulty in breathing and wheezing (bronchospasm)

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

If you notice any of the following side effects, tell your doctor:

- Kidney or liver problems or changes in the way your kidney functions. This may be noticed by the results of blood tests.

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

5. How to store TEİKOPOL

Keep TEİKOPOL out of the sight and reach of children, and in its original package.

Store at temperature below 25°C and in its original package.

The solution obtained by dissolution of the dry powder can be kept at 2-8°C for 24 hours in the refrigerator. This solution should not be frozen.

Solutions that are kept for more than 24 hours should not be used.

Use in compliance with the expiry date.

Do not use TEİKOPOL after the expiration date printed on its packaging. If you notice any irregularities in the product and/or its packaging, do not use TEİKOPOL.

Do not throw away expired or remained product! Please follow the local regulations.

Marketing Authorization Holder:
POLİFARMA İLAÇ SAN. VE TİC. A.Ş.
Vakıflar OSB Mahallesi, Sanayi Caddesi, No: 22/1
Ergene/Tekirdağ/TURKEY
Tel: +90 (282) 675 14 04

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Manufacturing Site (vial):
AROMA İLAÇ SANAYİ LTD. ŞTİ.
Vakıflar OSB Mahallesi, Sanayi Caddesi, No: 22/1 Kat: 2
Ergene/Tekirdağ/TURKEY
Tel: +90 (282) 675 10 06
Fax: +90 (282) 675 14 05

Manufacturing Site (solvent ampoule):
AROMA İLAÇ SANAYİ LTD. ŞTİ.
Vakıflar OSB Mahallesi, Sanayi Caddesi, No: 22/1 Kat: 2
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This patient leaflet was approved on 31/12/2019.

FOLLOWING INFORMATION IS INTENDED FOR MEDICAL OR HEALTHCARE PROFESSIONALS ONLY:

Preparation:

1. Draw up the entire contents of the water ampoule into a syringe.

2. Remove the vial's clear plastic cover by gently pushing it upwards.

3. Inject all of the water into the vial SLOWLY; approximately 0.2 ml of water will remain in the syringe.

4. Roll the vial gently between your hands until the powder is completely dissolved; taking care to avoid formation of foam. MAKE SURE THAT ALL POWDER, EVEN THOSE AROUND THE STOPPER, ARE COMPLETELY DISSOLVED.

Shaking this solution will form a foam which makes it difficult to obtain the expected volume. However, if TEİKOPOL is fully dissolved, the foam does not change the concentration of the solution and a concentration of 100 mg for 1.5 ml or 200 mg for 3 ml (200 mg vial) or 400 mg for 3 ml (400 mg vial) is obtained. If the solution becomes foamy then allow to stand for about 15 minutes.

5. Gently draw up the solution through the vial by placing the needle in the middle of the stopper and trying to remove most of the TEİKOPOL solution.

6. The concentration of a carefully prepared solution will be 100 mg in 1.5 ml (200 mg vial), 200 mg in 3 ml (200 mg vial) and 400 mg in 3 ml (400 mg vial). Correct preparation and careful withdrawal of the solution are important. Administration with carelessly prepared preparations result in the delivery of less than 50% of the dose.

7. Final solution is an isotonic solution with a pH of 7.2 to 7.8.

8. Reconstituted solution may be injected directly or diluted with the following:

- 0.9% Sodium chloride injection
- Sodium lactate compound injection (Ringer-Lactate solution, Hartmanns solution)
- 5% Dextrose injection
- 0.18% Sodium chloride and 4% Dextrose injection
- Peritoneal dialysis solutions containing 1.36% or 3.86% Dextrose

TEİKOPOL and aminoglycoside solutions are incompatible when mixed directly and should not be mixed before injection.

9. Vial content dissolved in distilled water should be kept in the refrigerator at 2-8°C for 24

hours, should not be frozen. Solutions that are kept for more than 24 hours should not be used.