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 subcutaneous tissue: Sometimes called “soft tissue”.
- Urinary tract
- Lungs
- Joint and bones
- 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.
- Blood: If any of the conditions listed above are caused by.

TEIKOPOL can be used to treat certain infections in the gut caused by bacteria called *Clostridium difficile*. In this case, the solution is taken orally.

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 one of these conditions, tell your doctor or pharmacist before using Teikopol;

- You have kidney problems
- You are allergic to an antibiotic called ‘vancomycin’
- If redness has occurred in the upper part of your body (red man syndrome)
- If your blood platelet count is low (thrombocytopenia).
- You are using or recently used to take other medicines which may cause hearing problems and/or kidney problems. You may need to have regular tests to check that your kidneys and / or liver are working properly.

If these warnings are valid for you, even at any time in the past, please consult your doctor.

Tests

You may need to have some tests done to check your blood, kidneys, and / or hearing ability during your treatment. This may be more necessary in the following situations:

• if your treatment will continue for a long time,

• you have kidney disease,

• you are using or are using medicines that can affect your nervous system, kidneys, or hearing.

In people who use TEİKOPOL for a long time, bacteria that are not affected by antibiotics can grow more than normal. Your doctor will check this.

Using TEİKOPOL with food and beverages

TEİKOPOL is used by injecting intravenously or intramuscularly. However, it can be used orally to treat antibiotic-induced diarrhea caused by a bacteria called *Clostridium difficile*. When TEİKOPOL is administered orally, it is not absorbed from the gastrointestinal tract. In healthy cases, when 250 or 500 mg single dose was administered orally, teicoplanin was not detected in serum or urine, but only unchanged medicinal product was detected in the stool (45% of the administered dose).

There are no data on its interaction with food.

Pregnancy

Please consult your physician or pharmacist before taking the drug.

If you are pregnant, think you may be pregnant or plan to become pregnant, consult your doctor before using this medicine. Your doctor will decide whether you should use TEİKOPOL. There may be a potential risk of developing inner ear and kidney problems. No problems with reproductive ability were encountered in experiments with animals.

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.

If you are breastfeeding, inform your doctor before you start using TEİKOPOL. Your doctor will decide whether you should breastfeed while using TEİKOPOL.

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
Inform your doctor if you are using other medicines, have recently used, or are likely to use them. Because TEİKOPOL may affect the way some medicines work, at the same time, other drugs can affect the way TEİKOPOL works. Inform your doctor, especially if you are taking the following medicines:

- Medicines used to treat infections: aminoglycoside antibiotics (including gentamicin, streptomycin, neomycin, kanamycin, amikacin, tobramycin). It can cause hearing problems and/or kidney problems. Aminoglycosides should not be mixed with TEİKOPOL in the same injection.
- Medicines for fungal infections (amphotericin B). It can cause hearing problems and/or kidney problems.
- Cyclosporine - A drug that affects the immune system and can cause hearing problems and/or kidney problems.
- Cisplatin - used in some types of cancer. It can cause hearing problems and/or kidney problems.
- Diuretic agents (such as furosemide). Also called diuretics, it can cause hearing problems and/or kidney problems.

If any of the above applies to you (or you are not sure), talk to your doctor before you start using TEİKOPOL.

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:
<u>In adults and children (12 years old and above) without kidney disease:</u>
Skin and soft tissue infections, lung infections, urinary tract infections

- Initial dose (for the first three doses): 6 mg per kilogram of body weight administered by intravenous or intramuscular injection every 12 hours.
- Maintenance dose: 6 mg per kilogram of body weight administered by intravenous or intramuscular injection once a day.

Joint and bone infections and heart infections

- Initial dose (for the first three to five doses): every 12 hours, 12 mg per kilogram of body weight administered by intravenous injection.
- Maintenance dose: 12 mg per kilogram of body weight administered by intravenous or intramuscular injection once a day.

Infection caused by *'Clostridium difficile'* bacteria
The recommended dose is 100 mg to 200 mg by mouth twice daily for 7 to 14 days.

Method of administration:
It is administered by intramuscular injection (intramuscular) or intravenous injection (intravenous).
•It can also be given by intravenous infusion. Infants up to two months from birth should be administered infusion only. In the treatment of certain infections, the solution can be taken by mouth.

Different age groups:
Use in children:
In infants (up to 2 months from birth)

- Initial dose (on the first day): 16 mg per kilogram of body weight administered by intravenous infusion.
- Maintenance dose: 8 mg per kilogram of body weight administered by intravenous infusion once a day.

In children (2 months to 12 years old)

- Initial dose (for the first three doses): every 12 hours, 10 mg per kilogram of body weight administered by intravenous injection.
- Maintenance dose: 6 to 10 mg per kilogram of body weight administered by intravenous injection once a day.

Special cases:
Adults and elderly patients with kidney problems
If you have kidney problems, your dose will usually need to be reduced after the fourth day of your treatment:

- In patients with mild to moderate kidney problems, the maintenance dose will be given every two days or half the maintenance dose once a day.
- In patients with severe kidney problems or in hemodialysis, the maintenance dose will be given every three days or one-third of the maintenance dose once a day.

Peritonitis for patients on peritoneal dialysis
The starting dose is 6 mg per kilogram of body weight, as a single injection into the vein.
Followed by:

- First week: 20 mg/L to each dialysis bag
- Second week: 20 mg/L to each other dialysis bag
- Third week: 20 mg/L overnight dialysis bag

If you have an impression that the effect of TEİKOPOL is too strong or weak, talk to your doctor or pharmacist.

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:
Since TEİKOPOL will be used under the supervision of a doctor, necessary measures will be taken to prevent such a situation. However, if you think that TEİKOPOL is given too much, talk directly to your doctor. If this is a mistake, the necessary treatment will be applied in the clinic.

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:
Since TEİKOPOL will be used under the supervision of a doctor and the applications will be made by qualified medical personnel, it will not be possible to forget the application of the drug. However, if you are concerned, talk to your doctor.

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

Possible effects once TEİKOPOL treatment is concluded:
Since TEIKOPOL treatment will definitely be applied under the supervision of a doctor, the doctor will decide to stop the treatment. However, if you leave the treatment without your doctor's approval, your complaints about your body system where the infection has settled may reappear and your overall health may deteriorate. If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

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

Side effects are listed as shown in the following categories:
Very common: It can be seen in at least one of 10 patients.
Common: Less than one in 10 patients, but more than one in 100 patients.
Uncommon: Less than one in 100 patients, but more than one in 1,000 patients.
Rare: Less than one in 1,000 patients, but more than one in 10,000 patients.
Very rare: Less than one in 10,000 patients can be seen.
Unknown: It cannot be estimated from the available data.

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

Uncommon:
- It may include life-threatening, sudden allergic reaction, rash, itching, fever, difficulty breathing or wheezing, chills, swelling.

Rare:
- Redness in the upper body

Unknown:
- Formation of water-filled blisters in the skin, mouth, eyes and genital area. This may be "Stevens Johnson syndrome" or "toxic epidermal necrolysis" or drug reaction (DRESS) with eosinophilia and systemic symptoms. DRESS is primarily manifested by flu-like symptoms and a rash on the face, followed by high fever, a rash, an increase in liver enzyme levels in blood tests, and an increase in a type of white blood cell (eosinophilia) and a growth in lymph nodes.

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:
Uncommon:
- Swelling or clotting in the vein
- Difficult and wheezing breathing (bronchospasm)
- Have more frequent infections than normal. This can be a sign of a decrease in the number of blood cells.

Unknown:
- Decrease in the number of white blood cells. Symptoms can include: Fever, severe tremors, sore throat, sores in the mouth (agranulocytosis).
- Kidney-related problems or changes in how your kidneys work with tests
- Sara-shaped seizures

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

If you notice any of the following side effects, tell your doctor:
Common:
- Rash, rash, itching;
- Pain
- Fire

Uncommon:
- Decrease in the number of blood flakes
- Increased level of liver enzymes in the blood
- Increased level of creatinine in the blood (to track your kidneys)
- Hearing loss, ringing in the ears, or feeling that you or those around you are moving.
- Being sick or feeling (vomiting), diarrhea
- Dizziness or headache

Rare:
- Infection (abscess)

Unknown:
- Problems such as redness, pain or swelling of the skin at the injection site

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 room 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.

Do not dispose of expired or unused drugs! Give to the collection system determined by the Ministry of Environment and Urbanization.

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
Fax: +90 (282) 675 14 05

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
Ergene/Tekirdağ/TURKEY
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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.