

TEICO[®] 200mg, Powder for Injection

TEICO[®] 400mg, Powder for Injection

Teicoplanin

Keep this leaflet. You might need to read it again

If you have any questions, talk to your doctor or pharmacist.
This medicine has been prescribed for you. Do not give it to anyone else. It could be harmful to them, even if their symptoms are identical to yours.
If you get any side effects talk to your doctor or pharmacist. This also applies to any side effects that are not mentioned in this leaflet. See section 4.

What is in this leaflet?

1. What is TEICO 200mg and TEICO 400mg, Powder for Injection, and in what cases is it used?

2. What you need to know before using TEICO 200mg and TEICO 400mg, Powder for Injection.

3. How to use TEICO 200mg and TEICO 400mg, powder for injection?

4. What are the possible side effects?

5. How to store TEICO 200mg and TEICO 400mg, powder for injection?

6. Contents of the package and other information.

1. WHAT IS TEICO 200mg and TEICO 400mg, Powder for Injection and WHAT IS IT USED FOR

TEICO is indicated in adults and children, starting from birth, for the parenteral treatment of the following infections: • complicated infections of the skin and soft tissues, • bone and joints infections, • nosocomial pneumonia, • community-acquired pneumonia, • complicated urinary tract infections, • infective endocarditis, • peritonitis associated with continuous ambulatory peritoneal dialysis (CAPD), • bacteremia occurring in combination with any of the above-mentioned indications. TEICO is also indicated as an oral therapeutic alternative for the treatment of diarrhea and colitis associated with Clostridium difficile infection. In some cases, teicoplanin should be given in combination with other antibacterials.

2. What you need to know before using TEICO 200mg and TEICO 400mg, Powder for Injection.

Do not use TEICO 200mg and TEICO 400mg, powder for injection:

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

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before using TEICO 200mg and TEICO 400mg Powder for Injection if:

You are allergic to an antibiotic called "vancomycin"

You redness on the upper part of your body (red man syndrome)

You have a decrease in the number of your platelets (thrombocytopenia)

You have kidney problems

You are taking other medicines that may cause hearing and / or kidney problems. Testing may be necessary at regular intervals to verify that your blood, kidneys and / or liver are working properly (see "Other medicines and TEICO").

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before using TEICO.

During your treatment, tests may be necessary to check your blood, kidneys and / or hearing. This will be more likely if:

You must be treated for a long period of 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 are taking TEICO for a long time, bacteria that are insensitive to this antibiotic can multiply; the doctor will need to check that.

Other medicines and TEICO 200mg and TEICO 400mg, Powder for Injection.

As your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This is because TEICO may affect the mode of action of some other medicines. Likewise, some medicines may also affect the way TEICO works.

Antibiotics: tell your doctor, pharmacist or nurse if you are taking any of the following medicines:

Amnoglycosides, because they must not be mixed with TEICO in the same injection. They can also cause hearing problems and / or kidney problems.

Amphotericin B, a medicine that treats fungal infections (mycosis) and can cause hearing problems and / or kidney problems.

Cisplatin, a medicine that affects the immune system and can cause hearing problems and / or kidney problems.

Cyclosporin, a medicine that treats malignant tumors and can cause hearing problems and / or kidney problems.

Duretics (such as furosemide), which 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, pharmacist or nurse before using TEICO.

TEICO 200mg and TEICO 400mg, powder for injection, with food and drinks.

Not applicable.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to get pregnant, ask your doctor, pharmacist or nurse for advice before using this medicine. He/she will decide whether or not you can use this medicine if you are pregnant or breastfeeding. A risk of injury to the inner ear or kidney problems are possible.

Animal reproduction studies have not shown evidence of impaired fertility.

Driving and using machines

You may experience headache or dizziness while taking TEICO. If this happens, do not drive or use tools or machinery.

TEICO 200mg and TEICO 400mg, powder for injection contains sodium.

3. How to use TEICO 200mg and TEICO 400mg, powder for injection?

The recommended dose is:

Adults and children (starting from 12 years) without kidney problems

Initial dose: for the first three doses: 6 mg per kilogram of body weight administered every 12 hours, by injection into a vein or muscle.

Maintenance dose: 6 mg per kilogram of body weight administered once daily by injection into a vein or muscle.

Bone and joint infections and heart infections

Initial dose: for the first three to five doses: 12 mg per kilogram of body weight given every 12 hours, by injection into a vein.

Maintenance dose: 12 mg per kilogram of body weight administered once daily by injection into a vein or muscle.

Infection due to "Clostridium difficile" bacteria

The recommended dose is 100 to 200 mg orally, twice a day for 7 to 14 days.

Children and elderly patients with kidney problems

If you have kidney problems, it will usually be necessary to reduce your dose after the fourth day of treatment. For people with mild to moderate kidney problems, the maintenance dose will be administered every two days, or half of the maintenance dose will be given once a day.

For people with severe kidney problems or on hemodialysis, the maintenance dose will be administered every three days, or one-third of the maintenance dose will be given once a day.

Peritonitis in a patient on peritoneal dialysis

The initial dose is 6 mg per kilogram of body weight, as a single injection into a vein, followed by:

Week One: 20 mg / L in each dialysis pack

Week two: 20 mg / L in one out of two dialysis bags

Week three: 20 mg / L in the night dialysis bag

Newborns and Infants (from birth to 2 months of age)

Initial dose (the first day): 16 mg per kilogram of body weight, by drip infusion into a vein.

Maintenance dose: 8 mg per kilogram of body weight, once a day by drip infusion into a vein.

Children (from 2 months to 12 years old)

Initial dose: for the first three doses: 10 mg per kilogram of body weight administered every 12 hours by injection into a vein.

Maintenance dose: 6 to 10 mg per kilogram of body weight given once a day by injection into a vein.

How to use TEICO

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

By injection into a vein (intravenous) or into a muscle (intramuscular route).

It can also be administered by drip infusion into a vein.

Newborns and infants (from birth to 2 months of age, should only receive this drug by infusion.

For the treatment of certain infections the solution can be taken orally.

If you have used more TEICO 200mg and TEICO 400mg Powder for Injection than you should have:

It is unlikely that your doctor or nurse will give you an excessive amount of this medicine. However, if you think you have used an excessive amount of TEICO or feel agitated, tell your doctor or nurse immediately.

If you forget to use TEICO 200mg and TEICO 400mg, Powder for Injection:

Your doctor or nurse will have instructions on when to give you TEICO. It is unlikely that he/she will not give you this medicine as prescribed. However, if you have forgotten, talk to your doctor or nurse.

If you stop using TEICO 200mg and TEICO 400mg, Powder for Injection:

Do not stop using this medicine without first talking to your doctor, pharmacist or nurse.

If you have any further questions about the use of this medicine, ask your doctor, pharmacist or nurse for more information.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Like in any other medicine, side effects might occur, although they are not systematic in all patients.

Serious side effects

Stop treatment and tell your doctor or nurse immediately if you notice any of the following serious side effects - you may need urgent medical treatment:

(Incummon may affect up to 1 in 100 people)

Sudden life-threatening allergic reaction - signs may include: difficulty breathing or wheezing, swelling, rash, itching, fever, chills.

Rare (may affect up to 1 in 1,000 people)

Reddening of the upper body

Undetermined frequency (can not be estimated from the available data)

Blisters on the skin, in the mouth or on the eyes or on the genitals - these may be signs of a "toxic epidermal necrolysis" or "Stevens-Johnson syndrome" or a reaction to the drug; drug hypersensitivity reaction with eosinophilia and

systemic symptoms (DRESS). DRESS is initially manifested by flu-like symptoms and a prolonged facial rash followed by fever, an increase in liver enzymes observed in blood tests, an increase in one type of white blood cell (eosinophils) and the swelling of the lymph nodes.

If you experience any of the above-mentioned side effects, talk to your doctor or nurse right away.

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

(Incummon may affect up to 1 in 100 people)

Swelling and clot in a vein

Difficulty breathing or wheezing (bronchospasm)

Increased susceptibility to infections - this may be a sign of a decrease in the number of your blood cells

Undetermined frequency (can not be estimated from the available data)

Insufficient number of white blood cells - signs may include fever, severe chills, sore throat or mouth ulcers (granulocytopenias)

Kidney problems or changes in the functioning of your kidneys - revealed by tests

Epileptic seizures

Difficulty with any of the above side effects, talk to your doctor or nurse right away.

Other adverse effects

If you notice any of the following side effects occur, tell your doctor, pharmacist or nurse:

Frequent (may affect up to 1 in 10 people)

Eruption, erythema, pruritus

Pain

Fever

(Incummon may affect up to 1 in 100 people)

Increase in the number of platelets

Increase blood levels of enzymes from the liver

Increased blood creatinine (measured to monitor your kidneys)

Hearing loss, ringing in the ears, or feeling that you or objects around you are moving

Nausea (feeling sick) or vomiting, diarrhea

Dizziness or headache

Rare (may affect up to 1 in 1,000 people)

Injection (abscess).

Undetermined frequency (can not be estimated from the available data)

Reaction at the injection site, such as reddening of the skin, pain or swelling

Reporting Side Effects

If you notice any side effects, tell your doctor or pharmacist. This also applies to any undesirable effects that are not mentioned in this leaflet. You can also report side effects directly via the national reporting system.

By reporting side effects, you can help provide more information on the safety of the medicine.

LEMOYNE/TEICO 200mg and TEICO 400mg, Powder for injection?

Keep away from heat.

After reconstitution and dilution: the product remains its activity for 24 hours at 2°C-8°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is mentioned on the packaging and on the vial label after EXP.

The expiry date refers to the last day of the mentioned month.

This medicine does not require any special storage precautions.

Do not use this medicine after the expiry date which is mentioned on the packaging and on the vial label after EXP.

"Practical information for health professionals on the preparation and handling of TEICO".

Do not dispose of any medication in the sewage system or garbage. Ask your pharmacist to eliminate medications you no longer use. These medicines should be recycled in the environment.

6. CONTENTS OF PACKAGING AND OTHER INFORMATION

What TEICO 200mg and TEICO 400mg contains, powder for injection

The active substance is teicoplanin.

For TEICO 200mg: Each vial contains 200 mg teicoplanin.

For TEICO 400mg: Each vial contains 400 mg teicoplanin.

The other ingredients are: Sodium Chloride and Sodium Hydroxide.

What is TEICO 200mg and TEICO 400mg, Powder for Injection and the contents of the pack

TEICO is a powder for injection containing in type I clear glass vials in packs of 1 vial and 10 vials.

Marketing Authorization Holder and Manufacturer

Med'S Laboratories

LES LABORATOIRES MEDIS

Road of Tunisie - KM 7 - BP 206 - 8000 Nabeul - Tunisia

Tel: (216) 72 23 50 06, Fax: (216) 72 23 50 16.

E-mail: contact@labomedis.com

Prescription and dispensing condition: List I

MA Number :

TEICO 200mg, box of 01 vial + 1 ampoule of solvent: 923 361 1H

TEICO 400mg, box of 01 vial + 1 ampoule of solvent: 923 361 2H

TEICO 200mg, pack of 10 vials: 923 361 3H

TEICO 400mg, box of 10 vials: 923 361 4H

Last revision date of this leaflet: 01/2020

Other

The following information is intended exclusively for health professionals:

Practical information for health professionals regarding the preparation and reconstitution of TEICO.

This medicine is for single use only.

Administration mode

The injection may be administered as a bolus over 3 to 5 minutes or by infusion over 30 minutes.

Infants from birth to 2 months of age should only receive this medicine by infusion.

The reconstituted solution can also be administered orally.

Preparation of the reconstituted solution

Slowly inject all the physical supplied into the powder vial.

Gently rotate the bottle between your hands until the powder is completely dissolved. If the solution becomes foamy, it should be left standing for about 15 minutes.

Reconstituted solutions contain 200 mg in 3.0 mL, and 400 mg in 3.0 mL.

Use only clear, yellowish solutions.

The final solution is isotonic with plasma and its pH is from 7.2 to 7.8.

Nominal amount of teicoplanin in the vial	200 mg	400 mg
Volume of the powder vial	15 mL	15 mL
Volume containing a nominal dose of teicoplanin (extracted with a 5 mL syringe and a 23G needle)	3.0 mL	3.0 mL

Preparation of the diluted solution before infusion

TEICO can be administered in the following infusion solutions:

Sodium Chloride Solution 9 mg / mL (0.9%)

Ringer's solution

Ringer's lactate solution

5% Dextrose Injection Solution

10% Dextrose Injection Solution

0.18% Sodium Chloride Solution and 4% Glucose

0.45% Sodium Chloride Solution and 5% Glucose

Solution for peritoneal dialysis containing 1.36% or 3.86% glucose solution.

Conservation period of the reconstituted solution

The chemical and physical stability of the reconstituted solution prepared according to the recommendations has been demonstrated for 24 hours at 2-8 ° C.

However, from a microbiological point of view, the drug should be used immediately. In case of non-immediate use, storage time and conditions after reconstitution / dilution and before use are the sole responsibility of the user and should not exceed 24 hours at a temperature between 2 and 8 ° C, unless the reconstitution has been prepared under validated and controlled aseptic conditions.

Conservation period of the diluted medicinal product

The chemical and physical stability of the reconstituted solution prepared according to the recommendations has been demonstrated for 24 hours at 2-8 ° C.

However, from a microbiological point of view, the drug should be used immediately. In case of non-immediate use, the storage times and conditions after reconstitution / dilution and before use are the sole responsibility of the user and should not exceed 24 hours at a temperature between 2 and 8 ° C, unless the reconstitution / dilution has been prepared under validated and controlled aseptic conditions.

Dilution

Any unused medicine or waste must be disposed of in accordance with the existing regulations.

This is a medicine

- A medicine is a product but not like any other product.

- A medicine is a product that affects your health if it's not used properly: it can be health threatening.

- Strictly adhere to the prescription of your Doctor and the use instructions prescribed, follow your pharmacist advice.

- Your doctor and you pharmacist know the medicine, its use and side effect.

- Don't stop the use of the treatment on your own during the prescribed time.

- Don't retake, Don't increase the doses without doctor's advice.

Keep the medicines out of reach of children