

TEICO[®] 200 mg
TEICO[®] 400 mg
Powder for solution for injection or infusion
Teicoplanin

Read all of this leaflet carefully before you start taking this medicine.

- 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 symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Teico is and what it is used for
2. Before you take Teico
3. How to take Teico
4. Possible side effects
5. How to store Teico
6. Further information

1. What Teico is and what it is used for?

Pharmaco-therapeutic group:

Teico is an antibiotic. It contains a medicine called "teicoplanin". It works by killing the bacteria that cause infections in your body.

Therapeutic indications:

Teico is used in adults and children (including newborn babies) to treat bacterial infections of:

- the skin and underneath the skin - sometimes called 'soft tissue'
- the bones and joints
- the lung
- the urinary tract
- the heart - sometimes called 'endocarditis'
- the abdominal wall - peritonitis
- the blood, when caused by any of the conditions listed above

2. Before you take Teico:

a- Do not take Teico:

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

b- Take special care with Teico:

Talk to your doctor or pharmacist before you are given Teico if:

- you are allergic to an antibiotic called "vancomycin"
- you have a flushing of your upper part of your body (red man syndrome)
- you have a decrease in platelet count (thrombocytopenia)
- you have kidney problems
- you are taking other medicines which may cause hearing problems and/or kidney problems. You may have regular tests to check if 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 or pharmacist before you are given Teico.

Tests

During treatment you may have tests to check your kidneys and/or your hearing. This is more likely if:

- your treatment will last for a long time
- you have a kidney problem

Tell your doctor if you are taking other medicines that may affect your nervous system, kidneys or hearing.

In people who are given Teico for a long time, bacteria that are not affected by the antibiotic may grow more than normal

- your doctor will check for this.

c- Taking other medicines, herbal or dietary supplements

In particular, tell your doctor or pharmacist if you are taking the following medicines:

- Aminoglycosides as they must not be mixed together with Teico in the same injection. They may also cause hearing problems and/or kidney problems.
 - Amphotericin B - a medicine that treats fungal infections which may cause hearing problems and/or kidney problems
 - cisplatin - a medicine that treats malignant tumors which may cause hearing problems and/or kidney problems
 - Water tablets (such as furosemide) - also called 'diuretics' which may cause hearing problems and/or kidney problems.
- Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines without prescription. This is because Teico can affect the way some other medicines work. Also, some medicines can affect the way Teico works.

d- Pregnancy and breast-feeding

If you are pregnant, think that you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before being given this medicine.

They will decide whether or not you are taking this medicine while you are pregnant. There may be a potential risk of inner ear and kidney problems.

In particular, tell your doctor or pharmacist if you are taking this medicine.

They will decide whether or not you can keep breast-feeding, while you are given Teico. Studies in animals reproduce have not shown evidence of fertility problems.

Ask your doctor, health care provider or pharmacist for advice before taking any medicine.

e- Driving and using machines

You may have headaches or feel dizzy while being treated with Teico. If this happens, do not drive or use any tools or machines.

Teico contains sodium:

This medicine contains sodium.

3. How to take Teico

Always take Teico exactly as your doctor or health care provider has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is Adults and children (12 years and over) with no kidney Problems

Skin and soft tissue, lung and urinary tract infections

- Starting dose (for the first three doses): 400 mg (this equates to 6 mg for every kilogram of body weight), given every 12 hours by injection into a vein or muscle
- Maintenance dose: 400 mg (this equates to 6 mg for every kilogram of body weight), given once a day, by injection into a vein or muscle

Bone and joint infections, and heart infections

- Starting dose (for the first three to five doses): 800 mg (this equates to 12 mg for every kilogram of body weight), given every 12 hours, by injection into a vein or muscle
- Maintenance dose: 800 mg (this equates to 12 mg for every kilogram of body weight), given once a day, hours, by injection into a vein or muscle

Adults and elderly patients with kidney problems

- If you have kidney problems, your dose will usually need to be lowered after the fourth day of treatment;
- For people with mild and moderate kidney problems - the maintenance dose will be given every two days, or half of the maintenance dose will be given once a day;
- For people with severe kidney problems or on haemodialysis - the maintenance dose will be given every three days, or one-third of the maintenance dose will be given once a day.

Peritonitis for patients on peritoneal dialysis

The starting dose is 6 mg for every kilogram of body weight, as a single injection into a vein, followed by:

- Week one: 20 mg/L in each dialysis bag
- Week two: 20 mg/L in every other dialysis bag
- Week three: 20 mg/L in the overnight dialysis bag.

Babies (from birth to the age of 2 months)

- Starting dose (on the first day): 16 mg for every kilogram of body weight, as an infusion through a drip into a vein.
- Maintenance dose: 8 mg for every kilogram of body weight, given once a day, as an infusion through a drip into a vein.

Children from 2 months to the age of 2 months

- Starting dose (for the first three doses): 10 mg for every kilogram of body weight, given every 12 hours, by injection into a vein.
- Maintenance dose: 6 to 10 mg for every kilogram of body weight, given once a day, by injection into a vein.

How Teico is given

The medicine will normally be given to you by a doctor.

- It will be given by injection into a vein (intravenous use) or muscle (intramuscular use).

• It can also be given as an infusion through a drip into a vein. Only the infusion should be given in babies from birth to the age of 2 months.

a- If you take more Teico than you should

It is unlikely that your doctor will give you too much medicine. However, if you think you have been given too much Teico or if you are agitated, talk to your doctor or pharmacist straight away.

b- If you forget to take Teico

Your doctor will have instructions about when to give you Teico. It is unlikely that they will not give you the medicine as prescribed. However, if you are worried, talk to your doctor.

c- If you stop taking Teico

Do not stop having this medicine without first talking to your doctor or pharmacist. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

All medicines, this medicine can cause side effects, although not everybody gets them. **Serious side effects** Stop your treatment immediately and tell your doctor or health care provider straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:

Uncommon (may affect up to 1 in 100 people)

- Sudden life-threatening allergic reaction - the signs may include: difficulty in breathing or wheezing, swelling, rash, itching, fever, chills
- Rare (may affect up to 1 in 1000 people)
 - flushing of the upper body

Not known (frequency cannot be estimated from the available data)

- Blistering of the skin, mouth, eyes or genitals - these may be signs of something called 'toxic epidermal necrolysis' or 'Stevens-Johnson syndrome.'
- Tell your doctor straight away, if you notice any of the side effects above.

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

Uncommon (may affect up to 1 in 100 people)

- swelling and clotting in a vein

- difficulty in breathing or wheezing (bronchospasm)

- getting more infections than usual - these could be signs of a decrease in your blood cell count Not known (frequency cannot be estimated from the available data)
- lack of white blood cells - the signs may include: fever, severe chills, sore throat or mouth ulcers (agraulocytosis)
- kidney problems or changes in the way your kidneys work - shown in tests
- epileptic fits

Tell your doctor or nurse straight away, if you notice any of the side effects above.

Other side effects:

Talk to your doctor, pharmacist or nurse if you get any of these:

Common (may affect up to 1 in 10 people)

- rash, erythema, pruritus
- pain
- fever

Uncommon (may affect up to 1 in 100 people)

- decrease in platelet count.
- raised blood levels of liver enzymes
- raised in blood levels of creatinine (to monitor your kidney)
- hearing loss, ringing in the ears or a feeling that you, or things around you are moving
- feeling or being sick (vomiting), diarrhoea
- feeling dizzy or headache

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

- infection (abscess)
- Not known (frequency cannot be estimated from the available data)
 - problems where the injection was given, or such as reddening of the skin, pain or swelling

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

5. How to store Teico.

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

Store below 30°C.

Do not use Teico after the expiry date which is stated on the carton and label of the vial after EXP. The expiry date refers to the last day of that month.

Do not use Teico if you notice that the powder is not spongy and beige mass.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines safely. These measures will help to protect the environment. Information about storage and the time to use Teico, after it has been reconstituted and is ready to use, are described in the 'How to take Teico- Practical information for healthcare professionals on preparation and handling of Teico.'

6. Further information

a- What Teico contains:

Teico 200 mg

- The active substance is teicoplanin 200 mg

Teico 400 mg

- The active substance is teicoplanin 400 mg

The other ingredients are: sodium chloride, sodium hydroxide and water for injection.

b- What Teico looks like and contents of the pack:

Teico, powder for solution for injection or infusion is spongy and beige mass and it is available in the following strengths:

- Teico 200 mg, in type 1 glass vials.
- Teico 400 mg, in type 1 glass vials

The powder will be mixed with an appropriate fluid before being injected. Each strength of Teico is supplied in cartons containing 1 vial of powder for solution for injection or infusion and 1 vial of solvent.

c- Marketing Authorisation Holder and Manufacturer:

LES LABORATOIRES MEDIS, S.A.

Routte de Tunis - KM 7 - BP 206 - 8000 Nabeul - Tunisie

Tel: (216) 72 23 50 06

Fax: (216) 72 23 51 06

E-mail: marketing.ventes@medis.com.tn

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

Salehiah Trading Establishment

Medical equipment & pharmaceuticals

P.O.Box: 991, Riyadh 11421 - Kingdom of Saudi Arabia

Tel: 00 966 1 46 34 362

Fax: 00 966 1 46 34 362

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e- To report any side effect(s):

- Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- o Fax: +966-11-205-7662
- o Call NPC at +966-11-2038222. Exts: 2317-2356-2353-2354-2334-2340.
- o Toll free phone: 8002490000
- o E-mail: npc.drug@afda.gov.sa
- o Website: www.afda.gov.sa/npc

- Other GCC states:

- Please contact the relevant competent authority.

f- Council of Arab Health Ministers

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicinal product.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children

Council of Arab Health Ministers
 Union of Arab Pharmacists

The following information is intended for medical or healthcare professionals only: Practical information for healthcare professionals on preparation and handling of Teico.

This medicine is for single use only.

Method of administration

The reconstituted solution may be injected directly or alternatively further diluted.

The injection will be given either as a bolus over 3 to 5 minutes or as a 30-minutes infusion.

Only the infusion should be given in babies from birth to the age of 2 months.

Preparation of reconstituted solution

The solution is reconstituted by adding 3.2 ml of water for injection to the 200 mg and 400 mg powder vial. The water is slowly added to the vial which should be rotated until all the powder is dissolved to avoid foaming. If foam is developed, allow the solution to stand for approximately 15 minutes so that the foam disappears.

Only limpid slightly yellowish, particle free liquid should be used.

The final solution is isotonic with plasma and has a pH of 7.2-7.8.

Nominal teicoplanin content of vial	200 mg	400 mg
Volume of powder vial	15 ml	15 ml
Volume containing nominal teicoplanin in dose (extracted by 9.5 ml syringe and 23 G 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 9 mg/ml, (0.9%) solution
- Ringer solution
- Ringer-lactate solution
- 5% dextrose injection
- 10% dextrose injection
- 0.18% sodium chloride and 4% glucose solution
- 0.45% sodium chloride and 5% glucose solution
- 0.9% sodium chloride and 5% glucose solution
- 1.36% and 3.86% glucose solution.

Shelf life of reconstituted solution

Chemical and physical in-use stability of the reconstituted solution as recommended has been demonstrated for 24 hours at 2 to 8°C. From a microbiological point of view, the medicine should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Shelf life of diluted medicine

Chemical and physical in-use stability of the reconstituted solution prepared as recommended has been demonstrated for 24 hours at 2 to 8°C. From a microbiological point of view, the medicine should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Disposal

Any unused medicine or waste material should be disposed of in accordance with local requirements.

