

Tostaf® 500
Powder for solution for infusion
Vancomycin

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.

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1. What Tostaf 500 is and what it is used for?

Pharmacotheapeutic group:

Vancomycin is an antibiotic.

Therapeutic indications:

It is used in potentially life-threatening infections, caused by gram-positive organisms, which will respond to vancomycin but which would not respond to other, less toxic antibiotics.

2. Before you take Tostaf 500:

a. Do not take Tostaf 500 if:

- If you have shown signs of hypersensitivity (severe allergy) to vancomycin in the past Tell your doctor if the above applies to you before this medicine is used.

b. Take special care with Tostaf 500 if you:

- If you have kidney problems
- If you have hearing difficulties Tell your doctor if either of the above applies to you before this medicine is used.

Special care will also be taken if you are elderly or you are due to have a general anaesthetic.

c. Taking other medicines:

Special care is needed if you are taking/using other medicines as some could interact with vancomycin, for example: • Other antibiotics that can affect your kidneys e.g. streptomycin, neomycin, gentamicin, kanamycin, amikacin, tobramycin, polymyxin B and colistin • Water tablets e.g. ethacrynic acid and frusemide • cholestyramine (a medicine used to treat high levels of fat in the blood or diarrhoea in inflammatory diseases of the gut). Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

d. Pregnancy and breast-feeding

Tell your doctor if you are pregnant, trying to become pregnant or breastfeeding. Your doctor will decide if you should receive this medicine. Ask your doctor, health care provider or pharmacist for advice before taking any medicine.

e. Driving and using machines

Do not drive or use machines if you experience any side effect (e.g. dizziness) which may lessen your ability to do so.

3. How you take Tostaf 500

Always take Tostaf 500 exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure. This medicine will be dissolved in Water for Injections and further diluted in e.g. 0.9% sodium chloride, before it is given to you. It will usually be given as a slow infusion via a drip into a vein. The infusion may last 20 - 60 minutes and be repeated during the day or it may be given as a continuous infusion over 24 hours.

Dose

Your doctor will work out the correct dose of vancomycin for you and how often it must be given. The dose of medicine given to you will depend on your age, the infection you have, how well your kidneys are working, if you have poor hearing and any other medicines you may be taking. Your doctor will tell how well your kidneys are working using blood or urine samples. It will take at least 2 or 3 days for you to respond to vancomycin. The length of the course of treatment depends on the infection being treated and may last a number of weeks.

During treatment you will undergo blood tests, be asked to provide urine samples and possibly have hearing tests to look for signs of toxic side effects. Blood tests will also be used during treatment to check the level of vancomycin in your blood.

a- If you take Tostaf 500 mg more than you should

This medicine will be given to you by a doctor or health care provider. It is unlikely that you will be given too much or too little, however, tell your doctor or health care provider if you have any concerns. If you have any further questions on the use of this product, ask your doctor, health care provider or pharmacist.

4. Possible side effects

Like all medicines, vancomycin can cause side effects, although not everybody gets them.

If any of the following happen, tell your doctor immediately:

- Severe allergic reaction - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint

- Chest pain
 - hearing loss or ringing in your ears
 - Blistery rash or scaling of the skin
 - Fast heart beat, palpitations or breathlessness
 - Dizziness or feeling faint
- These are serious side effects. You may need urgent medical attention. If any of the following happen, tell your doctor as soon as possible:
- Widespread skin rash which may be itchy
 - Fever, chills, shivering
 - Muscle spasms
 - A change in the amount or colour of urine
 - Fluid retention
 - Pain, swelling, redness or itching at the injection site
 - feeling sick or vomiting
 - Diarrhoea

Vancomycin may lead to changes in your blood cells and kidney function. Your doctor may take blood samples to check for these.

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 Tostaf 500

- Keep out of the reach and sight of children.
- Keep the vial in the outer carton, in order to protect from light, and store at or below 30°C.
- Do not use Tostaf 500 after the expiry date which is stated on the label and carton of the vial after EXP. The expiry date refers to the last day of that month.

• The reconstituted solution should be used immediately, however, if this is not possible it can be stored for up to 4 days in a refrigerator, provided it has been prepared in a way to exclude microbial contamination.

- Do not use Tostaf 500 if you notice that the solution is discoloured or contains particles.

• Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

a- What Tostaf 500 contains:

The active ingredient of Tostaf 500 is Vancomycin Hydrochloride. One vial contains 512.57 mg Vancomycin Hydrochloride, corresponding to 500 mg Vancomycin base.

- There are no other ingredients.

b- What Tostaf 500 looks like and contents of the pack:

Tostaf 500, powder for solution for infusion is a white hydrophilic compact mass. Tostaf 500, powder for solution for infusion is available in one presentation. It is presented in a type I glass vial. Unit pack containing 1 vial.

c- Marketing Authorization Holder and Manufacturer:

LES LABORATOIRES MEDIS- S.A.

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For any information about this medicinal product, please contact the

local representative of the Marketing Authorisation Holder:

Salehiya Trading Establishment

(Medical equipment & pharmaceuticals)

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

Tel: 00 966 1 46 46 955

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This leaflet was last approved in: 11/2015 ; version number: V00

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, Ext: 5193-2317-2356-2340.

o Toll free phone: 8002490000

o E-mail: npc.drug@sda.gov.sa

o Website: www.sda.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 medicament.

- 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