

SECTION 1: PATIENT INFORMATION LEAFLET (PIL)

Vancomycin

500 mg powder for solution for infusion and oral solution and oral solution

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- **Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, ask your doctor, pharmacist or nurse.**
- **This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.**
- **If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.**

In this leaflet:

1. **SERIOUS SIDE EFFECTS**
2. **WHAT VANCOMYCIN IS AND WHAT IS USED FOR**
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1. SERIOUS SIDE EFFECTS

Get emergency medical help if you have any of these signs of severe allergic reaction:

- hives
- difficulty breathing, closing of the throat
- serious peeling or blistering of the skin
- swelling of your face, lips, tongue, or throat/

Call your doctor at once if you have:

- pain or tight feeling in your back or chest
- flushing (warmth, redness, or tingly feeling) especially in your neck
- a light-headed feeling, like you might pass out
- itching, rash, wheezing, trouble breathing

- diarrhea that is watery or bloody
- swelling, pain, burning, irritation, or skin changes where the injection was given
- fever, swollen gums, painful mouth sores, pain when swallowing, skin sores, cold or flu symptoms, cough, trouble breathing
- hearing loss, ringing in your ears; or
- signs of a kidney problem - blood in your urine, little or no urinating, drowsiness, rapid weight gain.

Side effects on the kidneys may be more likely in older adults using this medicine.

2. WHAT VANCOMYCIN IS AND WHAT IS USED FOR

The name of your medicine is either Vancomycin 500mg powder for solution for infusion and oral solution and oral solution or Vancomycin 1g powder for solution for infusion and oral solution and oral solution, referred to as Vancomycin throughout the rest of this leaflet. Vancomycin contains the active ingredient vancomycin hydrochloride, which is an antibiotic. It is one of a group of medicines called glycopeptide antibiotics. It works by killing bacteria, which can cause serious infections. Vancomycin is made into a solution for intravenous infusion or a solution for oral use. This solution is given to you as an infusion, a slow injection, by means of a drip. It can also be given by mouth.

Vancomycin is used in all age groups to treat severe infections that are resistant to certain other antibiotics. It is used in patients who have not responded to treatment with, or have had a bad reaction to, other, better tolerated, antibiotics such as penicillins and cephalosporins. It is used to treat various severe infection of the lining or valves of the heart, lung tissue infection (pneumonia, lung abscess), bone infection (osteomyelitis), joints infection, skin and muscle (soft tissue) infections, brain infections. Vancomycin may be used to treat bacterial infection of the blood (septicemia) which might be associated with a type of infection mentioned above.

Vancomycin is used in patients with heart valve disease (e.g., rheumatic fever) or prosthetic (artificial) heart valves who are allergic to penicillin. Under certain circumstances, vancomycin is also given with other medicines to prevent endocarditis (inflammation of the lining of the heart) in patients who are having dental work done or surgery on the upper respiratory tract (e.g., nose or throat). It can also be given to you before some surgical procedures to prevent other infections.

Vancomycin can be given orally in adults and children for the treatment of two specific bacterial gut infections, namely, staphylococcal enterocolitis and pseudomembranous colitis (caused by *Clostridium difficile*).

3. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VANCOMYCIN

a. Do not use Vancomycin if:

- if you are allergic to vancomycin. An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

If you are not sure, ask your doctor or healthcare professional.

b. Talk to your doctor, pharmacist or nurse before using Vancomycin if:

- you suffered a previous allergic reaction to teicoplanin because this could mean you are also allergic to vancomycin.

c. Take special care with Vancomycin if:

- you have a hearing disorder, especially if you are elderly (you may need hearing tests during treatment)
- you have kidney disorder (you will need to have your blood and kidneys tested during treatment).

If you suffer from kidney failure or receive concomitant treatment with other substances toxic to kidney the possibility of developing toxic effects is much higher. Your doctor may perform several tests to see if your kidneys and liver are working properly.

If you are elderly or have kidney problems your doctor may also perform regular tests on your hearing and measure the amount of vancomycin in your blood.

Deafness, transitory or permanent, which may be preceded by noises in ears, can occur in patients with prior deafness, who have received excessive doses, or who receive treatment with another substance toxic to hearing.

To reduce this risk, blood levels should be checked periodically and periodic testing of hearing function is recommended.

d. Tell your doctor if you are taking any other medicines, especially:

- gentamycin (medicines for the treatment of infections caused by bacteria)
- amphotericin B (medicines for the treatment of fungal infections)
- streptomycin (medicines for the treatment of tuberculosis)
- neomycin (medicines for the treatment of infections caused by bacteria)
- kanamycin (medicines for the treatment of infections caused by bacteria)
- amikacin (medicines for the treatment of infections caused by bacteria)
- tobramycin (medicines for the treatment of infections caused by bacteria)
- bacitracin (medicines for the treatment of infections caused by bacteria)
- polymixin B (medicines for the treatment of infections caused by bacteria)

- colistin (medicines for the treatment of infections caused by bacteria)
- viomycin (medicines for the treatment of tuberculosis)
- cisplatin (medicinal product used to treat some types of cancer).

The following can also react with vancomycin if taken at the same time:

- anesthetic agents (if you are going to have a general anesthesia)
- muscle relaxants (used sometimes during a general anesthesia).

Please tell your doctor or nurse, if you are taking or have taken recently any other medicines, including medicines obtained without a prescription.

e. Pregnancy, breast-feeding and fertility

- If you are, or think you may be, pregnant, tell your doctor. Your doctor will then decide whether you should receive Vancomycin.
- Tell your doctor if you are breast-feeding as Vancomycin passes into breast milk. Your doctor will decide, if vancomycin is clearly needed or if you must stop breast-feeding.

f. Driving and using machines

Vancomycin has no or very little effect on your ability to drive and operate machines.

g. Important information about some of the ingredients of Vancomycin

This medicinal product contains less than 1mmol sodium (23mg) per vial, i.e. essentially 'sodium-free'.

4. HOW TO TAKE VANCOMYCIN

Vancomycin is given to you by hospital staff, using an infusion, (a slow injection by means of a drip). Each infusion will be given slowly, usually lasting for at least one hour. It may also be given to you to drink or via a tube in your nose. The dose given to you will depend on your age, your weight, the infection you have, how well your kidneys are working, your hearing ability any other medicines you may be taking.

How much you will receive

Intravenous administration

For patients whose kidneys are working normally

Adults and adolescents above 12 years of age: the usual dose is 2000mg daily in two or four doses (either 500mg every 6 hours or 1g every 12 hours).

Children (from one month to 12 years of age): the usual intravenous dosage is 10mg/kg per dose given every 6 hours (total daily dosage 40mg/kg of body weight).

Preterm and term newborn infants (from 0 to 27 days)

The dosage will be calculated according to post-menstrual age (time elapsed between the first day of the last menstrual period and birth (gestational age) plus the time elapsed after birth (post-natal age)).

The elderly, pregnant women and patients with a kidney disorder, including those on dialysis, may need a different dose.

For patients whose kidneys are not working normally

The doctor will reduce the dose or extend the interval between two doses. Special tests will be carried out and the dose will be adjusted to meet the results of the tests. If you are elderly, your doctor will also consider how well your kidneys are likely to be working.

Oral administration

Adults and adolescents above 12 years of age: The recommended dose is 125 mg every 6 hours. In some cases, your doctor may decide to give a higher daily dose of up to 500 mg every 6 hours. The maximum daily dose should not exceed 2 g.

Children: The recommended dose is 10 mg for each kg of body weight. It is usually given every 6 hours. The maximum daily dose should not exceed 2 g.

Your doctor will decide when your treatment should end.

a. If you take more Vancomycin than you should

As vancomycin will be given to you whilst you are in hospital it is unlikely that you will be given too little or too much, however, tell your doctor or nurse if you have any concerns.

b. If you stop using Vancomycin:

Do not stop having Vancomycin until your doctor tells you to.

If you still feel unwell at the end of your prescribed course of treatment, tell your doctor.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

5. POSSIBLE SIDE EFFECTS

Like all other medicines Vancomycin can cause side effects although not everybody gets them. If you have a severe allergic reaction (see section 1 of this leaflet), stop having Vancomycin and see a doctor straight away. You may need urgent medical treatment.

Rapid injection of Vancomycin may cause low blood pressure, difficulty breathing, itchy skin rash, redness of the skin of the upper body, pain and cramp in chest or back muscle can occur. Stopping the infusion usually results in a prompt cessation of the reactions.

Injection site pain, inflammation of the vein wall and blood clotting can occur and is occasionally severe, slow administration also reduces these side effects.

The following side effects may happen with this medicine:

Common side effects (affect 1 to 10 users in 100):

- decrease in blood pressure
- swelling, redness and pain along a vein
- shortness of breath (dyspnea)
- rash and inflammation of the lining of the mouth, itching, itching rash, hives
- redness of the upper body and the face, pain and contraction of the chest and back muscles
- kidney problems which may be detected primarily by increased creatinine or urea concentrations in your blood.

Rare side effects (affect 1 to 10 users in 10 000):

- anaphylactic reactions, allergic reactions
- loss of hearing
- spinning sensation (vertigo)
- dizziness
- ringing in the ears (tinnitus)
- drug fever, chills
- increased or reduced (sometimes severely decreased) urine output, or traces of blood in urine
- increase or decrease in some of the cells in the blood
- noises (e.g. hissing) in ears
- feeling faint
- red or purple skin (possible signs of blood vessel inflammation)
- nausea.

Very rare side effects (affect less than 1 out of 10 000 patients):

- skin disorders resulting from an allergic reaction (multiple skin lesions, joint aches);
- cardiac arrest;
- inflammation of the bowel which causes abdominal pain or bloody diarrhea.

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

- being sick (throwing up), diarrhea
- confusion, drowsiness, lack of energy, swelling, fluid retention, decreased urine

- rash with swelling or pain behind the ears, in the neck, groin, under the chin and armpits (swollen lymph nodes), abnormal blood and liver function tests
- rash with blisters and fever.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

6. HOW TO STORE VANCOMYCIN AND OTHER INFORMATION

Keep out of reach and sight of children

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

Store the unopened vial below 30°C. Keep container in the outer carton.

After reconstitution:

After reconstitution, the reconstituted concentrate should be diluted immediately.

Further diluted solution:

Chemical and physical in-use stability of the solution prepared for infusion has been demonstrated at 2-8 °C for 14 days when diluted in 0.9% Sodium Chloride Injection or 5% Glucose Injection, and for 4 days when diluted in Ringer's Injection. From a microbiological point of view, unless the method of reconstitution/dilution precludes the risk of microbial contamination, the product should be used immediately.

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 protect the environment.

7. FURTHER INFORMATION

a. What Vancomycin contains

The active substance is vancomycin (as hydrochloride).

There are no other ingredients.

Vancomycin 500 mg powder for solution for infusion and oral solution: Each vial contains: 500 mg vancomycin (as vancomycin hydrochloride) equivalent to not less than 525,000 IU

When reconstituted with 10 ml of water for injections, the resulting concentrate for solution for infusion contains 50 mg/ml vancomycin.

Vancomycin 1000 mg powder for solution for infusion and oral solution: Each vial contains: 1000 mg vancomycin (as vancomycin hydrochloride) equivalent to not less than 1,050,000 IU.

When reconstituted with 20 ml of water for injections, the resulting concentrate for solution for infusion contains 50 mg/ml vancomycin.

b. What Vancomycin looks like

Vancomycin is a homogeneous, white to cream coloured powder.

It is supplied in colorless glass vials sealed with an aluminum seal or flip-off aluminum seal with 1, 10, 1-50 or 50 vials in a carton.

Not all pack sizes may be marketed.

c. Marketing Authorisation Holder and Manufacturer

“KRASPHARMA” OJSC

Russia, 660042, 60 let Oktyabrya st. 2, Krasnoyarsk

Tel.: +7 (391) 261-25-90. Fax: +7 (391) 261-17-44

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

“KRASPHARMA” OJSC

Russia, 660042, 60 let Oktyabrya st. 2, Krasnoyarsk

Tel.: +7 (391) 261-25-90. Fax: +7 (391) 261-17-44

d. This leaflet was last approved _____; version number _____.

e. To report any side effect(s):

- _____:

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Fax: _____

Call _____ at _____, Exts: _____.

Toll free phone: _____

E-mail: _____@_____

Website: _____

f. Council of _____

THIS IS A MEDICAMENT

- **A 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 experts in medicine, its benefits and risks.**
- **Do not by yourself interrupt the period of treatment prescribed.**
- **Do not repeat the same prescription without consulting your doctor.**
- **Keep medicament out of reach of children**

g. This patient information leaflet is approved by the _____.