

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Vancocin CP 1 g powder for solution for infusion (Vancomycin)

Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- 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 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.

What is in this leaflet

1. What Vancocin CP is and what it is used for
2. What you need to know before you use Vancocin CP
3. How to use Vancocin CP
4. Possible side effects
5. How to store Vancocin CP
6. Contents of the pack and other information

1. What Vancocin CP is and what it is used for

Your medicine is called Vancocin CP. The active substance is lyophilised vancomycin as vancomycin hydrochloride. Your medicine is in glass vials that are kept in the hospital. They contain 1 g of vancomycin.

The nurse or doctor will reconstitute Vancocin CP powder with a suitable sterile solution (sodium chloride, dextrose, etc.).

Vancomycin is an antibiotic that belongs to a group of antibiotics called “glycopeptides”. Vancomycin works by eliminating certain bacteria that cause infections.

Vancomycin is used in all age groups by infusion for the treatment of the following serious infections:

- Infections of the skin and tissues below the skin;
- Infections of bone and joints;
- An infection of the lungs called “pneumonia”;
- Infection of the inside lining of the heart (endocarditis) and to prevent endocarditis in patients at risk when undergoing major surgical procedures;
- Infection in central nervous system;
- Infection in the blood linked to the infections listed above.

Vancomycin can be given orally in adults and children to treat infections of the lining of the small and large intestine, with damage to the lining (pseudomembranous colitis) caused by the bacterium *Clostridium difficile*.

2. What you need to know before you use Vancocin CP

Do not use Vancocin CP

- If you are allergic to vancomycin hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to teicoplanin, as cross-reactions have been reported hypersensitivity between vancomycin and teicoplanin.

Warnings and precautions

Serious side effects that may lead to loss of vision have been reported following the injection of vancomycin in the eyes.

Talk to your doctor or pharmacist or nurse before using Vancocin CP, if:

- You suffered a previous allergic reaction to teicoplanin because this could mean you are also allergic to vancomycin;
- 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);
- You are receiving vancomycin by infusion for the treatment of the diarrhoea associated to *Clostridium difficile* infection instead of orally;
- You have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking vancomycin.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP) have been reported in association with vancomycin treatment. Stop using vancomycin and seek medical attention immediately if you notice any of the symptoms described in section 4.

Talk to your doctor or pharmacist or nurse during treatment with Vancocin CP, if:

- You are receiving vancomycin for a long time (you may need to have your blood, hepatic and kidneys tested during treatment);
- You develop any skin reaction during the treatment;
- You develop severe or prolonged diarrhoea during or after using vancomycin, consult your doctor immediately. This may be a sign of bowel inflammation (pseudomembranous colitis) which can occur following treatment with antibiotics.

Children

Vancomycin will be used with particular care in premature infants and young infants, because their kidneys are not fully developed and they may accumulate vancomycin in the blood. This age group may need blood tests for controlling vancomycin levels in blood.

Concomitant administration of vancomycin and anaesthetic agents has been associated with skin redness (erythema) and allergic reactions in children. Similarly, concomitant use with other medicines such as aminoglycoside antibiotics, nonsteroidal anti-inflammatory agents (NSAIDs, e.g., ibuprofen) or amphotericin B (medicine for fungal infection) can increase the risk of kidney damage and therefore more frequent blood and renal test may be necessary.

Other medicines and Vancocin CP

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

This is particularly important if you are taking/using one of the following medicines:

- Medicines for the treatment of bacterial infections (other antibiotics, such as aminoglycosides (e.g. gentamicin) – the toxic effects on the kidneys and hearing increase);
- Medicines for fungal infections (amphotericin B);
- Medicines that suppress the activity of the immune system (ciclosporin);
- Diuretic medicines (loop diuretics);
- Medicines for cancer (cisplatin);

- Anaesthetics (if you are given a general anaesthetic);
- Medicines to relax the muscles during anaesthesia (muscle relaxants).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Vancocin CP should be administered during pregnancy only if absolutely necessary. Your doctor will decide whether you should be given Vancocin CP.

Breast-feeding

Tell your doctor, if you are breast-feeding, because Vancocin CP passes into breast milk. Your doctor will decide whether you must stop breast-feeding during treatment with Vancocin CP.

Driving and using machines

There are no data on the effect of Vancocin CP on the ability to drive or use machines, but the route of administration (hospital conditions) precludes the possibility of performing the activities in question.

3. How to use Vancocin CP

Always use Vancocin CP exactly as your doctor has told you. If you are not sure, talk to your doctor or pharmacist.

You will be given vancomycin by medical staff while you are in hospital. Your doctor will decide how much of this medicine you should receive each day and how long the treatment will last.

Dosage

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.

Intravenous administration

Adults and adolescents (from 12 years and older)

The dosage will be calculated according to your body weight. The usual infusion dose is 15 to 20 mg for each kg of body weight. It is usually given every 8 to 12 hours. In some cases, your doctor may decide to give an initial dose of up to 30 mg for each kg of body weight.

The maximum daily dose should not exceed 2 g.

Use in children

Children aged from one month to less than 12 years of age

The dosage will be calculated according to your body weight. The usual infusion dose is 10 to 15 mg for each kg of body weight. It is usually given every 6 hours.

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.

Oral administration

Adults and adolescents (12 to 18 years)

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.

If you have had other infections (mucosal infection), you may need a different dose and a different duration of treatment.

Use in children

Newborns, infants and children under 12 years of age

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

Method of administration

Intravenous infusion means that the medicinal product flows from an infusion bottle or bag through a tube to one of your blood vessels and into your body. Your doctor, or nurse, will always give vancomycin into your blood and not in the muscle.

Vancomycin will be given into your vein for at least 60 minutes.

If used to treat stomach conditions (so-called pseudomembranous colitis), the medicine should be given as a solution for oral use (you will take the medicine by mouth).

Duration of treatment

The length of treatment depends on the infection you have and may last a number of weeks.

The duration of the therapy may be different depending on the individual response to treatment for every patient.

During the treatment, you might have blood tests, be asked to provide urine samples and possibly have hearing tests to look for signs of possible side effects.

4. Possible side effects

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

Vancomycin can cause allergic reactions, although serious allergic reactions (anaphylactic shock) are rare. Tell your doctor immediately if you get any sudden wheeziness, difficulty in breathing, redness on the upper part of the body, rash or itching.

Stop using vancomycin and seek medical attention immediately if you notice any of the following symptoms:

- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome and toxic epidermal necrolysis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).

However, if you have an inflammatory disease of the digestive tract, especially if you also have a kidney problem, side effects may occur when vancomycin is given by infusion.

Common side effects (may affect up to 1 in 10 people):

- Fall in blood pressure;
- Breathlessness, noisy breathing (a high pitched sound resulting from obstructed air flow in the upper airway);
- Rash and inflammation of the lining of the mouth, itching, itching rash, hives;
- Kidney problems which may be detected primarily by blood test;
- Redness of upper body and face, inflammation of a vein.

Uncommon side effects (may affect up to 1 in 100 people):

- Temporary or permanent loss of hearing.

Rare side effects (may affect up to 1 in 1 000 people):

- Decrease in white blood cells, red blood cells and platelets (blood cells responsible for blood clotting);
- Increase in some of the white cells in the blood;
- Loss of balance, ringing in your ears, dizziness;
- Blood vessel inflammation;
- Nausea (feeling sick);
- Inflammation of the kidneys and kidney failure;
- Pain in the chest and back muscles;
- Fever, chills.

Very rare side effects (may affect up to 1 in 10 000 people):

- Sudden onset of severe allergic skin reaction with skin flaking blistering or peeling skin. This may be associated with a high fever and joint pains;
- Cardiac arrest;
- Inflammation of the bowel which causes abdominal pain and diarrhoea, which may contain blood.

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

- Being sick (throwing up), diarrhoea;
- 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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system of:

Bulgarian Drug Agency
8 Damyan Gruev Str.
1303 Sofia, Bulgaria
Tel.: +35 928903417
website: www.bda.bg

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

5. How to store Vancocin CP

Your doctor will be responsible for storage the medicine.

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

Do not store above 25 °C.

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

When Vancocin CP powder is already dissolved, the vial of the drug should be stored in a refrigerator (2 - 8 °C) and administered within 24 hours. And if it will be administered orally, then it can be stored in a refrigerator for up to 4 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Vancocin CP contains

- The active substance is: vancomycin hydrochloride. Each vial contains 1000 mg vancomycin hydrochloride, (equivalent to 1 000 000 IU).
- Vancocin CP does not contain excipients.

What Vancocin CP looks like and content of the pack

A carton box with 10 vials Vancocin CP and package leaflet for the patient.

Marketing Authorisation Holder and Manufacturer:

Tchaikapharma High Quality Medicines Inc.
1 G. M. Dimitrov Blvd, Sofia 1172, Bulgaria
Tel.: +359 2 962 54 54
FAX: + 359 2 9603 703
e-mail: info@tchaikapharma.com

Date of last revision of the text

February, 2022

Other sources of information

Advice/medical education

Antibiotics are used to cure bacterial infections. They are ineffective against viral infections.

If your doctor has prescribed antibiotics, you need them precisely for your current illness.

Despite antibiotics, some bacteria may survive or grow. This phenomenon is called resistance: some antibiotic treatments become ineffective.

Misuse of antibiotics increases resistance. You may even help bacteria become resistant and therefore delay your cure or decrease antibiotic efficacy if you do not respect appropriate:

- dosage;
- schedules;
- duration of treatment.

Consequently, to preserve the efficacy of this drug:

1. Use antibiotics only when prescribed.
2. Strictly follow the prescription.
3. Do not re-use an antibiotic without medical prescription, even if you want to treat a similar illness.
4. Never give your antibiotic to another person; maybe it is not adapted to her/his illness.
5. After completion of treatment, return all unused drugs to your chemist's shop to ensure they will be disposed of correctly.

The following information is intended for medical or healthcare professionals only:

Vancocin CP powder for solution for infusion should be administered as a slow intravenous infusion at a rate not exceeding 10 mg/min for at least 60 minutes or more.

Preparation of solution

The content of 1 vial is dissolved in 20 ml of water for injections and further diluted with other infusion solutions to 200 - 400 ml.

Suitable diluents are: 5% glucose solution for injection, 0.9% sodium chloride or 5% dextrose solution for infusion BP.

The concentration of vancomycin should not exceed 5 mg/ml. The solution should be inspected visually for precipitation or discoloration prior to use.

Shelf life of the reconstituted solution for infusion

After reconstitution: Solution can be stored in a refrigerator (2 - 8 °C) for 24 hours.

From a microbiological point of view, the reconstituted concentrate should be further diluted immediately after preparation and the medicinal product should be used immediately.

After reconstitution for oral use - 4 days when stored in the refrigerator.