PACKAGE LEAFLET: INFORMATION FOR THE USER

Vancomycin 125 mg Hard Capsules
vancomycin hydrochloride

Read all of this leaflet carefully before you start taking 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Vancomycin capsules are and what they are used for
2. What you need to know before you take Vancomycin capsules
3. How to take Vancomycin capsules
4. Possible side effects
5. How to store Vancomycin capsules
6. Contents of the pack and other information

1. What Vancomycin capsules are and what they are used for

Vancomycin capsules contain the active ingredient vancomycin. 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 adults and adolescents from 12 years of age for the treatment of infections of the mucosa of the small and the large intestines with damage to the mucosae (pseudomembranous colitis), caused by the *Clostridium difficile* bacterium.

2. What you need to know before you take Vancomycin capsules

Do not take Vancomycin capsules:
- If you are allergic to vancomycin or any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Vancomycin capsules
- If you have a kidney disorder (you will need to have your blood and kidneys tested during treatment)
- If you have an inflammatory disorder of the digestive tract (you may be at risk of side effects, especially if you also have a kidney disorder)
- If you are elderly (you may need your blood and hearing monitored)
- If you have a hearing disorder (you may need hearing tests during treatment)
- If you are receiving Vancomycin capsules for a long time (you may develop another type of infection)
- If 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.
- Signs of an allergic reaction to this medicine, including breathing problems and chest pain, have been reported with Vancomycin capsules. Stop immediately Vancomycin capsules and contact immediately your doctor or medical emergencies if you notice any of these signs.

Vancomycin capsules are not appropriate for children under 12 years or for adolescents unable to swallow them. Other forms of this medicine may be more suitable for children; ask your doctor or pharmacist.

Other medicines and Vancomycin capsules
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is especially important for the following, as they may interact with your Vancomycin capsules:

- any drug that harms your kidneys e.g. antibiotics such as gentamicin, tobramycin.
- any drug that harms your hearing e.g. antibiotics such as gentamicin, tobramycin.

It may still be alright for you to be given Vancomycin capsules and your doctor will be able to decide what is suitable for you.

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.

Driving and using machines
Vancomycin capsules should not affect your ability to drive or use machines.

3. How to take Vancomycin capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and adolescents (from 12 years and older)
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 suffered other episodes (infection of the mucosa) before you may need different dose and different duration of the therapy.

Method of administration

For oral use.

Swallow the capsules whole with water.

The usual duration of the therapy is 10 days but it may be different depending on the individual response to treatment for every patient.

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).
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Uptake of vancomycin from the gastrointestinal tract is negligible. Therefore, adverse events following intake of capsules are unlikely.

However, if you have an inflammatory disorder of the digestive tract, especially if you also have a kidney disorder, similar side effects as those that occur when vancomycin is given by infusion may appear. Therefore, the side effects and frequencies which are reported for vancomycin given as infusion are included.

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)
- Increase of liver enzymes
- Rash and inflammation of the lining of the mouth, itching, itching rash, hives
- Kidney problems which may be detected primarily by blood tests
- 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 blood 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
- Excessive breakdown of red blood cells causing tiredness and pale skin (haemolytic anaemia)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

5. How to store Vancomycin capsules

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

Do not store above 25°C. Store in the original blister in order to protect from moisture.

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.

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 to protect the environment.

6. Contents of the pack and other information

What Vancomycin capsules contain

The active substance is vancomycin hydrochloride 125mg.

The other ingredients are:
Macrogol 6000, gelatin, indigo carmine, red iron oxide, yellow iron oxide and titanium dioxide.

The printing ink contains:
Shellac, propylene glycol, iron oxide red (E172) and potassium hydroxide.

What Vancomycin capsules look like and contents of the pack
Vancomycin capsules are contained in blister packs of 20 capsules (2 strips of 10 capsules) or 28 capsules (4 strips of 7 capsules).
The capsules are dark blue and brown coloured and printed with the number 3125.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Flynn Pharma Ltd
5th Floor,
40 Mespil Road,
Dublin 4,
IRELAND, D04 C2N4

Manufacturer
MW Encap Limited
Units 1-8, Oakbank Park Way,
Oakbank Industrial Estate,
Mid Calder, Livingston,
EH53 0TH
United Kingdom

NextPharma Ploermel
Zone Industrielle De Camagnon
56800 Ploermel
France

This leaflet was last revised in
January 2026

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 any 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.