

Package leaflet: Information for the patient
Vancomycin 125 mg hard capsules
Vancomycin 250 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.

What is 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 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 hydrochloride 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 kidney problems, especially if you are currently taking other medicines that can affect the kidneys (see "Other medicines and Vancomycin capsules", below) because vancomycin can cause kidney damage;
- 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 suffer from deafness or ear problems;
- 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.

Children and adolescents

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.

In particular, tell your doctor if you are taking any of the following:

- other **antibiotics** such as streptomycin, neomycin, gentamycin, cephaloridine, polymixin B, colistin, tobramycin or amikacin. These medicines may affect your kidneys and/or hearing if you take them at the same time with vancomycin.

Vancomycin capsules with food, drink and alcohol

There is no data on the interaction of vancomycin with food, drink or alcohol.

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.

Talk to your doctor before starting treatment with this medicine if you are breast-feeding. This is because Vancomycin passes into breast milk.

Driving and using machines

This medicine is not known to affect your ability to drive and 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.

The usual recommended dose is:

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.

If you take more Vancomycin capsules than you should

If you take more capsules than prescribed, seek medical attention immediately.

If you forget to take Vancomycin capsules

Do not take a double dose to make up for a forgotten dose. Simply continue taking the capsules as before.

If you stop taking Vancomycin capsules

You must continue the course of treatment with vancomycin as prescribed by your doctor or pharmacist. If you stop taking vancomycin without finishing the course of treatment, there may be a risk that you will feel worse again.

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

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.

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,

Dimension - 180 x 260 mm

Front Side

ARTWORK DETAIL LABEL

Product	Vancomycin hard capsules 125 & 250 mg		
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert
Dimension	180 x 260 mm	Pack	--
New Item Code	1042360	Old Item Code	1035098
Colour Shades	BLACK	No. of Colours	1
Change Control No.	PC-TSG/2020/478 - Record Number: 285772		Artwork Version 5.0
Design/Style	Front & Back Printing. To be supplied in the unfolded size		
Substrate	60 GSM Paper.		
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.		
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.		
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.			

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.

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).

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 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.

Reporting of side effects

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

You can also report side effects directly via the national reporting system, Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Vancomycin capsules

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated

on the package, after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C.

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

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:

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

What Vancomycin capsules contains

- The active ingredient is vancomycin hydrochloride. Each hard capsule contains 125mg vancomycin hydrochloride (equivalent to 125,000 IU vancomycin) or 250 mg vancomycin hydrochloride (equivalent to 250,000 IU vancomycin).
- The other ingredient is polyethylene glycol (Macrogol) 6000.
- The capsule coating is made of gelatin and colorants.
- The capsules contain the following colorants:
 - Iron oxide Yellow (E172)
 - Iron oxide Red (E172)
 - Titanium dioxide (E171)
 - Iron Oxide Black (E172)

What Vancomycin capsules look like and contents of the pack

The 125 mg capsules are grey/pink hard gelatin capsules containing white to off white liquid mixture as solid mass. The 250 mg capsules are brown hard gelatin capsules containing white to off white liquid mixture as solid mass.

Original packs containing 4, 12, 20, 28 or 30 hard capsules. Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Strides Pharma UK Ltd.
Unit 4, Metro Centre, Tolpits Lane
Watford, Hertfordshire, WD18 9SS
United Kingdom

And
Dr. Friedrich Eberth Arzneimittel GmbH
Am Bahnhof 2
92289 Ursensollen

This leaflet was last revised in 01/2021.



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Back Side

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