PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

VANCOCIN® CP 500 mg (Powder for injection)

VANCOCIN® CP 1 g (Powder for injection)

Sugar free

Read all of this leaflet carefully before you are being administered VANCOCIN CP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- VANCOCIN CP has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What VANCOCIN CP is and what it is used for
2. What you need to know before you receive VANCOCIN CP
3. How to receive 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

VANCOCIN CP (Powder for injection) is an antibiotic which is used for patients with serious infections caused by vancomycin-sensitive organisms that are resistant to other antimicrobial agents, including the penicillins or cephalosporins.

VANCOCIN CP (Powder for injection) may be taken orally for treatment of staphylococcal enterocolitis and antibiotic-associated pseudomembranous colitis produced by *C. difficile*.

2. What you need to know before you receive VANCOCIN CP

Do not be administered VANCOCIN CP if:

You are allergic to vancomycin or any of the other ingredients in the powder for injection.

Take special care with VANCOCIN CP:

Talk to your doctor before being administered VANCOCIN CP (Powder for injection) if:

- Your kidney function is impaired.
- You have a history of loss of hearing or deafness.
- You are pregnant or breast feeding a baby.
- You have 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 generalised 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.
- You develop any skin reaction during the treatment.
- You develop eye disorders.
- You are below the age of 12, your doctor or healthcare professional will take precautions in administering VANCOCIN CP to you.
- You develop severe or prolonged diarrhoea during or after using VANCOCIN CP.
- You are receiving VANCOCIN CP for a long time (you may need to have your blood, liver and kidneys tested during treatment).
- You are taking or have previously taken aminoglycoside antibiotics (for e.g. neomycin or gentamycin).

Other medicines and VANCOCIN CP

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Please consult your doctor, pharmacist or other healthcare professional for advice if you are taking any of the following medication:

- Aminoglycoside antibiotics (for e.g. neomycin or gentamycin).
- Anaesthetics – these may cause redness of the skin, flushing or other infusion-related reactions.
- Medicines that may affect your nerves or kidneys such as amphotericin B (treats fungal infections), aminoglycosides, bacitracin, polymixin B, colistin, viomycin (antibiotics) or cisplatin (a chemotherapy drug), piperacillin/tazobactam.
- Loop diuretics such as furosemide.

Vancomycin infusion should be completed before the induction of anaesthesia, as some of the adverse effects of vancomycin may become worse by use of general anaesthetics at the same time as VANCOCIN CP (Powder for injection).

Your doctor and pharmacist will have more information on medicines to be careful with or to avoid while receiving VANCOCIN CP.

VANCOCIN CP with food and drink

Food or drink will not have any effect on the absorption of VANCOCIN CP (Powder for injection).

Pregnancy and breastfeeding

Pregnancy:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before being administered VANCOCIN CP (Powder for injection).

Vancomycin should be given during pregnancy and breast-feeding only if clearly needed. Your doctor will decide if you should be administered Vancomycin.

The safety of VANCOCIN CP (Powder for injection) in pregnant and breastfeeding women has not yet been established.

Breastfeeding:

Tell your doctor if you are breastfeeding, since Vancomycin passes into breast milk. Your doctor will decide whether vancomycin is really necessary or whether you should stop breastfeeding.

Driving and using machines

You should refrain from driving or using machinery until you know how this medicine affects your ability to concentrate.

3. How to receive VANCOCIN CP

Do not share medicines prescribed for you with any other person.

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

VANCOCIN CP (Powder for injection) is an injection which will be administered to you by your doctor. This injection must be administered directly into your vein. Your doctor may also mix VANCOCIN CP (Powder for injection) with other intravenous solutions and administer it as an intravenous infusion.

If you have the impression that the effect of VANCOCIN CP (Powder for injection) is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will decide on the appropriate dose based on:

- the bacteria that caused the infection
- the seriousness of the infection
- your weight (children)
- whether or not you have impairment of your kidney function.

VANCOCIN CP (Powder for injection) can also be given in specific circumstances as an oral solution to the patient to drink. The total daily dosage should not exceed 2 g if taken by mouth. The appropriate dose should be mixed in 30 ml of water and given to the patient to drink.

If you received more VANCOCIN CP than you should

Since your doctor will administer this medicine, he/she will control the dosage. However, in the event of overdosage, your doctor will treat the side effects symptomatically.

4. Possible side effects

VANCOCIN CP can have side effects.

Not all side effects reported for VANCOCIN CP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving VANCOCIN CP, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- hives (nettle rash)
- swelling of the face, lips, tongue or throat

- difficulty breathing or swallowing
- dizziness.

These are all very serious side effects. If you have them, you may have had a serious reaction to VANCOCIN CP. You may need urgent medical attention or hospitalisation.

Frequent side effects: decrease in blood pressure, thrombophlebitis, dyspnoea, stridor, exanthema and mucosal inflammation, pruritus, urticaria, redness of the upper body and face, pain and spasm of the chest and back muscles, renal insufficiency manifested primarily by increased blood concentrations of creatinine or urea.

Less frequent side effects: nausea, vomiting, change in the frequency of urination or amount of urine, a bitter or unpleasant taste in the mouth with the oral solution, stomach cramps and diarrhoea, ringing or buzzing in the ears.

Side effects of unknown frequency: syndrome that may cause a rash, fever, inflammation of internal organs, and characteristic abnormalities of your blood (so called "DRESS"), sudden formation of pustules within large swollen areas (so called "AGEP"), acute tubular necrosis.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of VANCOCIN CP. Suspected adverse reactions can also be reported directly to the Holder of the Certificate of Registration (HCR) via Patientsafety.sacg@novartis.com.

5. How to store VANCOCIN CP

Store the dry powder at or below 25 °C.

After reconstitution: When the powder for injection is mixed with water for injection, 5 % dextrose injection, or 0,9 % sodium chloride injection, the product is stable for 14 days when stored in a refrigerator (0 to 5 °C).

When the powder for injection is mixed with 5 % dextrose and 0,9 % sodium chloride injection, USP; lactated Ringer's injection, USP; lactated Ringer's and 5 % dextrose injection; Normosol-M and 5 % dextrose; Isolyte E; or acetated Ringer's injection, the product is stable for 96 hours when stored in a refrigerator (0 to 5 °C).

Do not use VANCOCIN CP (Powder for Injection) after the expiry date printed on the label.

Return the expired medicine to your pharmacist for safe disposal.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VANCOCIN CP contains

Each vial of VANCOCIN CP 500 mg and 1 g (Powder for injection) contains sterile vancomycin hydrochloride powder, equivalent to 500 mg or 1 g of vancomycin base respectively, as the active ingredient.

Inactive ingredients:

Water for injections

What VANCOCIN CP looks like and contents of the pack

VANCOCIN CP 500 mg (Powder for injection), is a 10 ml size vial sealed with a rubber stopper and an aluminium cap. It contains a white to off-white coloured, dry, sterile powder for injection. When mixed with water it is a clear and colourless to light-yellow solution.

VANCOCIN CP 1 g (Powder for injection), is a 20 ml size vial sealed with a rubber stopper and an aluminium cap. It contains a white to off-white coloured, dry, sterile powder for injection. When mixed with water it is a clear and colourless to light-yellow solution.

VANCOCIN CP 500 mg (Powder for injection) 10 ml vials are supplied in packs of 1 or 10.

VANCOCIN CP 1 g (Powder for injection) 20 ml vials are supplied in packs of 1 or 10.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

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2090

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Registration numbers

VANCOCIN CP 500 mg: C/20.1.1/181

VANCOCIN CP 1 g: X/20.1.1/23

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07