PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

MYLAN VANCOMYCIN 1 g (Powder for solution for infusion)

MYLAN VANCOMYCIN 500 mg (Powder for solution for infusion)

Vancomycin

Sugar free

Read all of this leaflet carefully before you are given MYLAN VANCOMYCIN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What **MYLAN VANCOMYCIN** is and what it is used for.

2. What you need to know before you take **MYLAN VANCOMYCIN**.

3. How to take **MYLAN VANCOMYCIN**.

4. Possible side effects.

5. How to store **MYLAN VANCOMYCIN**.

6. Contents of the pack and other information.

1. What MYLAN VANCOMYCIN is and what it is used for

MYLAN VANCOMYCIN is an antibiotic that belongs to a group of antibiotics called “glycopeptides". It works by eliminating certain bacteria that cause infections. **MYLAN VANCOMYCIN** is used for the treatment of certain serious infections when other medicines such as penicillin cannot be used because of allergy or inadequate efficacy.

2. What you need to know before MYLAN VANCOMYCIN is administered

MYLAN VANCOMYCIN should not be administered to you:

If you are hypersensitive (allergic) to vancomycin hydrochloride or any of the other ingredients of **MYLAN**

VANCOMYCIN (listed in section 6).

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection if:

• You suffered a previous allergic reaction to teicoplanin because this could mean you are also allergic to **MYLAN VANCOMYCIN**.

• You have a hearing disorder, especially if you are elderly (you may need hearing tests during treatment).

• You have a kidney disorder (you will need to have your blood and kidneys tested during treatment).

• You are receiving **MYLAN VANCOMYCIN** by infusion for the treatment of the diarrhoea associated with *Clostridium difficile* infection instead of orally.

Special care should be taken with MYLAN VANCOMYCIN:

• **MYLAN VANCOMYCIN** is usually administered as a slow infusion into your vein. If **MYLAN VANCOMYCIN** infusion is administered too fast, you may experience red man syndrome (high temperature, rash or redness of face, base of neck, upper body, back and arms, low blood pressure, nausea or vomiting, itching of skin) (see "How to receive **MYLAN VANCOMYCIN"**). These should subside when the treatment ends.

• If you are receiving **MYLAN VANCOMYCIN** for a long time (you may need to have your blood, liver and kidneys tested during treatment).

• If you develop any skin reaction during the treatment.

• If you develop severe or prolonged diarrhoea during or after using **MYLAN VANCOMYCIN**, consult your doctor immediately. This may be a sign of bowel inflammation (pseudomembranous colitis) which can occur following treatment with antibiotics.

• If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking **MYLAN VANCOMYCIN**.

• if you have previous deafness, received excessive intravenous doses or if you receive the treatment together with another ototoxic medicine such as aminoglycoside you may develop temporary or permanent hearing loss. Tell your doctor if you experience ringing in your ears as this may occur before hearing loss develops. To reduce the risk of

deafness or hearing loss, your doctor or healthcare professional will check your blood levels and ears regularly. Your doctor will also tell you which other medicines to avoid while receiving **MYLAN VANCOMYCIN**.

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalised exanthematous pustulosis (AGEP) have been reported in association with **MYLAN VANCOMYCIN** treatment. Seek medical attention immediately if you notice any of the symptoms described in section 4.

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

Children and adolescents

MYLAN 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.

Other medicines and MYLAN VANCOMYCIN

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

The following medicines may react with **MYLAN VANCOMYCIN** if you take them at the same time:

• Amphotericin B (medicine used to treat fungal infections)

• Aminoglycoside antibiotics:

- Streptomycin (used to treat serious infections)
- Gentamycin, amikacin (used to prevent or treat a wide variety of bacterial infections)
- Kanamycin (used to treat serious infections caused by bacteria)
- Tobramycin (used to treat eye infections)

• Neomycin (an antibiotic used to reduce the risk of infection during surgery of your intestines)

• Viomycin (used to fight infections of tuberculosis)

• Bacitracin (used to prevent minor skin infections)

• Polymyxins, colistin (used to prevent bacterial infections)

• Cisplatin (used to treat cancer)

• Loop diuretics (used in the treatment of oedema due to heart failure, liver disease and kidney disease). They may also be used to treat high blood pressure.

The above medicines may increase risk of serious ear and kidney effects and should be used with caution when receiving **MYLAN VANCOMYCIN**.

• General anaesthesia such as suxamethonium and vecuronium. The effect of these medicines may be increased when administered with **MYLAN VANCOMYCIN**.

• Concomitant administration of **MYLAN VANCOMYCIN** and anaesthetic medicines have been associated with skin redness (erythema) and allergic reactions in children.

• Similarly, concomitant use with other medicines such as aminoglycoside antibiotics, nonsteroidal anti-inflammatory drugs (NSAIDs, e.g. ibuprofen) or amphotericin B (medicine for fungal infection) can increase the risk of kidney damage and therefore more frequent blood and kidney tests may be necessary.

Your doctor may need to test your blood and adjust the dosage if **MYLAN VANCOMYCIN** is given simultaneously with other medicines.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before you are given this medicine.

The safe use of **MYLAN VANCOMYCIN** during pregnancy and breastfeeding has not been established.

Driving and using machines:

MYLAN VANCOMYCIN may make you feel dizzy and may impair your ability to drive and use machinery.

3. How to receive MYLAN VANCOMYCIN

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

You will not be expected to give yourself **MYLAN VANCOMYCIN**. It will be given to you by a person who is qualified to do so.

Your doctor will prescribe appropriate dose according to your condition.

MYLAN VANCOMYCIN will be injected into your vein as a slow drip.

Your doctor will work out your dose of **MYLAN VANCOMYCIN** according to your weight. It will also be based on your overall health, kidney function and other medicines you are taking.

The dosage is as follows:

If a patient has normal renal function:

Adults: The usual daily intravenous dose is 2 g divided either as 500 mg every 6 hours or 1 g every 12 hours.

Children: The total daily intravenous dose of **MYLAN VANCOMYCIN**, calculated on the basis of 40 mg/kg of body mass, can be divided and incorporated into the child's 24-hour fluid requirement.

Infants and neonates: The initial dose of 15 mg/kg is suggested, followed by 10 mg/kg every 12 hours in the first week of life and every 8 hours thereafter until one month of age. Blood concentrations will be monitored carefully.

Each dose should be administered at a rate of no more than 500 mg per half-hour.

If you have problems with your kidneys, your doctor will adjust your dose of **MYLAN VANCOMYCIN**.

For oral administration:

The usual adult total daily dosage for antibiotic-associated pseudomembranous colitis produced by *C. difficile* is 500 mg to 2 g to be given in three or four divided doses for 7 to 10 days. The total daily dosage in children is 40 mg/kg of body mass in three or four divided doses. The total daily dosage should not exceed 2 g. The appropriate dose should be diluted in 30 ml of water and given to the patient to drink. Common flavouring syrups should be added to

the solution to disguise the taste for oral administration.

If you receive more MYLAN VANCOMYCIN than you should:

Since a healthcare provider will administer **MYLAN VANCOMYCIN**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If a dose of MYLAN VANCOMYCIN is forgotten

Since a healthcare provider will administer **MYLAN VANCOMYCIN**, it is unlikely that the dose will be missed.

4. Possible side effects

MYLAN VANCOMYCIN can have side effects.

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

If any of the following happens, stop receiving **MYLAN VANCOMYCIN** and tell your doctor immediately or go to the casualty department at your nearest hospital:

• swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,

• rash or itching,

• fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

• Low blood pressure

• Swelling and blood clot in the arm

• Heart attack

• Blood problems such as a reduced number of white blood cells or platelets. This can cause frequent infections such as fever, severe chills, sore throat or mouth ulcers, bleeding or bruising more easily than normal.

• Rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals

• Hearing loss, buzzing, hissing, whistling, ringing or other persistent noise in the ears

• Inflammation of a blood vessel or in arteries

• Inflammation of the colon

• Acute kidney failure

• Severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell.

• Diarrhoea (watery stools)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

• Redness of the upper body and face

• Pain, tenderness or swelling especially near the injection site

Less frequent:

• Chest pain

• Back pain

• Neutropenia (decrease in a type of white blood cells which help your body fight infections)

• Hay fever

• Vertigo, dizziness, hearing loss, tinnitus

• Cardiac arrest

• Rashes

• Burning eyes

• Kidney failure

• Inflammatory bowel disease

Frequency unknown:

• Dizziness, spinning sensation

• Feeling sick (nausea)

• Vomiting

• High temperature

• Chills

• Ototoxicity (develops hearing or balance problems)

• Nephrotoxicity (rapid deterioration in the kidney function)

• Acute tubular necrosis (damage to the tubule cells of the kidneys)

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **MYLAN VANCOMYCIN**.

5. How to store MYLAN VANCOMYCIN

Before reconstitution: Store at or below 25 °C.

After reconstitution: With water for injection: Store at 2 – 8 °C or below 25 °C for up to 24 hours.

After dilution: With either 5 % glucose or 0,9 % sodium chloride: Store at 2 – 8 °C or below 25 °C for up to 24 hours.

DISCARD ANY UNUSED SOLUTION.

Keep the vial in the outer carton until required for use.

Do not use after the expiry date stated on the label/carton.

Store all medicines out of reach of children.

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

6. Contents of the pack and other information

What MYLAN VANCOMYCIN contains

The active substance is vancomycin hydrochloride.

Each **MYLAN VANCOMYCIN 500 mg** vial contains sterile vancomycin hydrochloride equivalent to 500 mg of vancomycin base per 10 ml of reconstituted solution.

Each **MYLAN VANCOMYCIN 1 g** vial contains sterile vancomycin hydrochloride equivalent to 1 g of vancomycin base per 20 ml of reconstituted solution.

The other ingredients are: hydrochloric acid (if necessary to adjust pH) and water for injection.

What MYLAN VANCOMYCIN looks like and contents of the pack

MYLAN VANCOMYCIN 500 mg (Powder for solution for infusion) contains a white to almost white or slightly pink or yellow freeze-dried powder for injection**.**

MYLAN VANCOMYCIN 1 g (Powder for solution for infusion) contains a white to almost white or slightly pink or yellow freeze-dried powder for injection.

Appearance of reconstituted solution: When reconstituted in water, it is a clear solution, free from visible particles.

Contents of the pack

MYLAN VANCOMYCIN 500 mg (Powder for solution for infusion): 10 ml type II clear glass vials sealed with dark grey bromobutyl rubber stoppers and over sealed with aluminium flip-off caps are supplied in packs of 1 or 10.

MYLAN VANCOMYCIN 1 g (Powder for solution for infusion): 20 ml type II clear glass vials sealed with dark grey bromobutyl rubber stoppers and over sealed with aluminium flip-off caps are supplied in packs of 1 or 10.

The vials are packed into an outer carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Republic of South Africa

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To be confirmed

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MYLAN VANCOMYCIN 1 g: 41/20.1.1/0572