Applicant/PHRC: ***Hetero Drugs South Africa (Pty) Ltd***

Product proprietary name: ***STAVANCE 500 mg & 1 g IV***

Dosage form and strength: ***Lyophilized powder for solution for infusion***
Each 20 ml vial contains vancomycin hydrochloride equivalent to vancomycin 500 mg
Each 30 ml vial contains vancomycin hydrochloride equivalent to vancomycin 1 g

PATIENT INFORMATION LEAFLET FOR STAVANCE 500 mg & 1 g IV

SCHEDULING STATUS: S4

STAVANCE 500 mg IV (lyophilized powder for solution for infusion)

STAVANCE 1 g IV (lyophilized powder for solution for infusion)

Vancomycin hydrochloride

STAVANCE is sugar free

Read all of this leaflet carefully before you are given STAVANCE

- 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.

What is in this leaflet

1. What STAVANCE is and what it is used for

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

cause infections. It is used for the treatment of certain serious infections when other medicines such as penicillin cannot be used because of allergy or are working inadequately.

2. What you need to know before STAVANCE is administered

STAVANCE should not be administered to you:

- If you are hypersensitive (allergic) to vancomycin hydrochloride teicoplanin (has similar use as vancomycin) or any of the other ingredients of **STAVANCE** (listed in section 6).

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you have kidney disease (you will need to have your kidneys tested during treatment).
- If you have hearing difficulties (you may need to have your hearing tested during treatment).

Special care should be taken with **STAVANCE**:

- **STAVANCE** is usually administered as a slow infusion into your vein. If **STAVANCE** is administered infusion 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 STAVANCE**). These should subside when the treatment ends.
- If you develop severe or prolonged diarrhoea during or after use of **STAVANCE** there is a possibility of pseudomembranous colitis (severe inflammation of the bowel characterized by pus and blood in the stool and often caused by antibiotics) developing. Tell your doctor or healthcare provider if you develop diarrhoea. This might be life-threatening and has to be taken into account. Your doctor or healthcare professional might even discontinue the therapy.

- if you have previous deafness, received excessive intravenous doses or if you receive the treatment together with another ototoxic substance 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 [**STAVANCE**.
- Serious skin reactions during the vancomycin treatment. Stop using vancomycin and seek medical attention immediately and SCAR (Severe cutaneous adverse reactions) with the use of vancomycin, treatment with vancomycin must not be restarted at any time.

Children and adolescents

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. Blood tests will be conducted routinely to control vancomycin levels in the blood.

Other medicines and STAVANCE

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines).

Tell your doctor if you are already taking medicines that contain any of the following:

- 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 STAVANCE.
- General anaesthesia such as suxamethonium and vecuronium. The effect of these medicines may be increased when administered with STAVANCE.
- Anaesthetic medicines have been associated with skin redness (erythema) and allergic reactions in children.
- Aminoglycoside antibiotics, nonsteroidal anti-inflammatory agents (NSAIDs, e.g., ibuprofen) or amphotericin B (medicine for fungal infection) can increase the risk of kidney damage.

STAVANCE with food, drink and alcohol

Since, **STAVANCE** is given through intravenous administration, will not be affected by food or drink.

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 health care provider for advice before you are given this medicine.

Driving and using machines

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

3. How to receive STAVANCE

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

You will not be expected to give yourself STAVANCE. 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.

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

[PRODUCT NAME will be injected into your vein as a slow drip.

Your doctor will work out your dose of **STAVANCE** according to your height and weight (body surface area). It will also be based on your overall health, kidney function and other medication you are taking.

Patients with 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 usual dose is calculated the basis of 40 mg/kg of body mass,

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.

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

For oral administration:

The usual adult total daily dosage for antibiotic-associated pseudomembranous colitis produced by C. difficile is 500 mg to 2 g 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 STAVANCE than you should

Since a health care provider will administer **STAVANCE**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If a dose of STAVANCE is forgotten

Since a health care provider will administer **STAVANCE**, it is unlikely that the dose will be missed.

4. Possible side effects

STAVANCE can have side effects.

Not all side effects reported for **STAVANCE** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving **STAVANCE**, please consult your health care provider for advice.

If any of the following happens, stop receiving **STAVANCE** 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 **STAVANCE**. 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 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
- 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 Adverse drug reaction and quality problem reporting form found online under SAHPRA's publications: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problemreporting-form/ or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more information on the safety of **STAVANCE**.

5. How STAVANCE will be stored

- **Before reconstitution:** store at or below 25 °C.
- **After reconstitution:** 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 contents
- Protect from light and moisture.
- Keep the vial tightly closed.
- Keep the vial in the outer carton until required for use.
- Store all medicines out of reach of children.
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle.

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

6. Contents of the pack and other information

What STAVANCE contains

- The active substance is vancomycin hydrochloride
- The other ingredients are hydrochloric acid, nitrogen NF, sodium hydroxide and water for injection

What STAVANCE looks like and contents of the pack

STAVANCE 500 mg IV: White to tan lyophilized cake or powder. When reconstituted as directed the solution should be clear, light to dark tan colored solution.

STAVANCE 1 g IV: White to tan lyophilized cake or powder. When reconstituted as directed the solution should be clear, light to dark tan colored solution.

Contents of the pack

STAVANCE 500 mg IV is supplied as a 20 ml round clear USP Type 1 tubular glass vial with a 20 mm grey colored bromo-butyl rubber stopper and a 20 mm sky blue colored poly propylene plastic button with lacquer coated aluminium flip off seal cap.

STAVANCE 1 g IV is supplied as a 30 ml round clear USP Type 1 tubular glass vial with a 20 mm grey colored bromo-butyl rubber stopper and a 20 mm grey colored poly propylene plastic button with lacquer coated aluminium flip off seal cap.

Each vial is placed in an outer carton.

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd

Waterfall corporate campus,

Building no. 2, first floor,

74 waterfall drive,

Midrand 2066

Tell: 0126441220.

This leaflet was last revised in

11 July 2023.

Registration number(s)

STAVANCE 500 mg IV: 54/20.1.1/0299.295.

STAVANCE 1 g IV: 54/20.1.1/0300.296.

Access to the corresponding Professional Information

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