

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LINOACT IV, 600 mg/300 mg solution for infusion

Linezolid

Contains sugar (glucose monohydrate 50,24 mg/ml solution)

Read all of this leaflet carefully before you are given

LINOACT IV

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

What is in this leaflet

1. What LINOACT IV is and what it is used for
2. What you need to know before LINOACT IV is administered to you
3. How LINOACT IV will be administered to you
4. Possible side effects
5. How to store LINOACT IV
6. Contents of the pack and other information

1. What LINOACT IV is and what it is used for

Linezolid is an antibiotic of the oxazolidinones group, that works by stopping the growth of certain bacteria (germs) that cause infections.

LINOACT IV may be prescribed by your doctor to treat certain infections, including pneumonia and some infections in the skin, or under

the skin. Your doctor will determine if LINOACT IV is suitable to be used for the type of infection you have.

2. What you need to know before LINOACT IV is administered to you

LINOACT IV should not be administered to you:

- if you are hypersensitive (allergic) to linezolid or any of the other ingredients of LINOACT IV (listed in section 6).
- if you are treated with monoamine oxidase inhibitors (examples of monoamine oxidase inhibitors (MAOIs) are phenelzine, isocarboxacid) or within 2 weeks of taking such a medicine. These medicines may have been prescribed for you for depression or Parkinson's disease.

LINOACT IV may not be suitable for you if you have any of the following medical conditions. In this case tell your doctor as he/she will need to check your general health and your blood pressure before and during your treatment or may decide another treatment is better for you.

Ask your doctor if you are not sure if you have any of these conditions:

- High blood pressure, and what medicines you are taking for this
- An overactive thyroid
- A tumour of the adrenal glands (phaeochromocytoma) or carcinoid syndrome (caused by tumours of the hormone system with symptoms of diarrhoea, flushing of the skin, wheezing)
- If you are taking any of the following medicines:

- Decongestant, cold or flu remedies containing pseudoephedrine or phenylpropanolamine
- Medicines used to treat Parkinson's disease (dopamine)
- Medicines used to treat heart failure (dobutamine)
- Antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors)
- Medicines used to treat anxiety (such as buspirone)
- Medicines used to treat moderate to severe pain, such as pethidine, meperidine.

Warnings and precautions

Special care should be taken with LINOACT IV.

Tell your doctor or healthcare provider before being given

LINOACT IV injection:

- if you already have loose bowels or have recently been treated with an antibiotic medicine. LINOACT IV may cause inflammation and infection of the bowels (see ***You should also know that***);
- if you have anaemia (have low red blood cells), as LINOACT IV may worsen the condition;
- if you tend to get infections, as LINOACT IV may cause a decrease in white blood cells;
- if you bruise or bleed easily, as LINOACT IV may cause a decrease in platelets;
- if you have a history of seizures ("fits"), as convulsions have been reported during treatment with LINOACT IV;

- if you have liver or kidney problems (especially if you have dialysis);

You should also know that:

- LINOACT IV may cause serious diarrhoea and infection in the bowels (see section 4, **Possible side effects**). You may develop diarrhoea during or after treatment with LINOACT IV. If this becomes severe or persistent or you notice that your stool contains blood or mucous, treatment with LINOACT IV should be stopped immediately and your doctor consulted. You should not take medicines that stop or slow bowel movement.
- High levels of serotonin (a chemical substance in your body) result when you also take other medicines, particularly selective serotonin reuptake inhibitors (SSRIs) for depression (see **Other medicines and LINOACT IV**). Tell your doctor about all these medicines and contact him/her immediately if you experience an altered mental state, including agitation, confusion, coma, stiff muscles, trembling, poor coordination and fits;
- Lactic acidosis may occur: Tell your doctor if you have muscle aches, burning, rapid breathing, nausea, stomach pain. See **Possible side effects**.
- LINOACT IV may cause inflammation of the optic nerve (see **Possible side effects**). Tell your doctor immediately if you have problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.
- Peripheral neuropathy may occur: This is a result of damage to your peripheral nerves that causes weakness, numbness and pain, usually

in your hands and feet. Tell your doctor if you take medicines for the treatment of tuberculosis (TB), as this may increase your risk to develop this condition. (See **Other medicines and LINOACT IV**).

Other medicines and LINOACT IV

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

- You should not receive LINOACT IV if you are currently taking or have taken MAOIs within the last 14 days (for example phenelzine, isocarboxazid, selegiline, moclobemide). These may be used to treat depression or Parkinson's disease. See **PRODUCT NAME should not be administered to you**.
- Your doctor may consider using another medicine if you currently take/use or have recently used the following medicines:
 - Decongestant cold or flu remedies containing pseudoephedrine or phenylpropanolamine.
 - Medicines used to treat sudden, severe allergic reactions such as epinephrine (adrenaline).
 - Medicines which increase your blood pressure, such as norepinephrine (noradrenaline), dopamine and dobutamine.
 - Certain antidepressants known as tricyclics or SSRIs. There are many of these, including amitriptyline, clomipramine, fluoxetine, fluvoxamine, imipramine, paroxetine and sertraline.
 - Medicines used to treat anxiety disorders, such as buspirone.
 - Medicines used to treat moderate to severe pain, such as pethidine and meperidine.
 - Medicines that stop blood clotting, such as warfarin.

- An antibiotic for tuberculosis (TB) called rifampicin.

LINOACT IV with food and drink

Avoid eating large amounts of mature cheese, yeast extracts, or soya bean extracts e.g. soy sauce and drinking alcohol, especially draught beers and wine. This is because linezolid (as in LINOACT IV) may react with a substance called tyramine which is naturally present in some foods and so cause an increase in your blood pressure. If you develop a throbbing headache after eating or drinking, tell your doctor or pharmacist immediately.

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 receive LINOACT IV.

The effect of LINOACT IV in pregnant women is not known; it should therefore not be used during pregnancy.

Reproductive toxicity was demonstrated in animals.

Linezolid (contained in LINOACT IV) decreased fertility in animals. The possible effect on the human male reproductive system has not been established.

You should not breastfeed your baby while receiving LINOACT IV because it passes into breast milk and could affect the baby.

Driving and using machines

LINOACT IV may make you feel dizzy or experience problems with your vision (see **Possible side effects**). Do not drive or use tools or machines if this happens, as LINOACT IV could interfere with your ability to drive safely.

LINOACT IV contains glucose and sodium

Glucose

Each 1 ml of LINOACT IV contains 50,24 mg glucose monohydrate (15,072 g glucose monohydrate in one bag of 300 ml solution). This should be taken into account in patients with diabetes mellitus. Tell your doctor if you have an intolerance to some sugars, before receiving LINOACT IV.

Sodium

Each 1 ml of LINOACT IV solution contains 0,44 mg sodium (131,49 mg sodium in one bag of 300 ml solution). Please tell your doctor or nurse if you are on a low sodium diet.

3. How LINOACT IV will be administered to you

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

LINOACT IV is normally administered in hospital.

Your doctor will tell you how long your treatment with LINOACT IV will last. Do not stop treatment early, since a full course of antibiotic treatment is necessary to kill the germs that made you ill (see **If you stop using LINOACT IV**).

The usual dose is:

Adults:

- LINOACT IV will be infused (dripped) into a large vein over a period of 30 to 120 minutes.
- Your doctor will consider your type of infection and medical condition when deciding on a dose. Typical doses are 600 mg every 12 hours. The treatment may last between 10 and 28 days, depending on your infection and response.

Children:

- The dose of LINOACT IV depends on your child's body weight and severity of infection. Typical doses are 10 mg/kg every 8 hours, administered via an intravenous drip. The treatment may last from 10 to 28 days, depending on your child's infection and response.

If you receive haemodialysis, your doctor will administer the LINOACT IV dose after the dialysis procedure.

If you have the impression that the effect of LINOACT IV is too strong or too weak, tell your doctor or pharmacist.

If you receive more LINOACT IV than you should

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

Tell your doctor or health care provider at once if you think you may have been given too much LINOACT IV.

If you missed a dose of LINOACT IV

Since a healthcare provide will administer LINOACT IV, it is unlikely that the dose will be missed.

If you think that you have missed a dose of treatment, tell a doctor or nurse at once. Do not take a double dose to make up for a forgotten dose.

If you stop using LINOACT IV

To clear up your infection completely, LINOACT IV should be used for the full course of treatment as prescribed by your doctor.

Your symptoms may improve before the infection is completely treated. Stopping treatment too early may help the germs causing the infection to become resistant to LINOACT IV.

4. Possible side effects

LINOACT IV can have side effects.

Not all side effects reported for LINOACT IV are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving LINOACT IV, please consult your healthcare provider for advice.

LINOACT IV is administered in a hospital setting. Your medical condition will be carefully monitored by a healthcare provider.

Tell your healthcare provider immediately if you notice any of the following:

- Serious allergic reactions, including a shock reaction. This may include swelling of the tongue and/or throat, difficulty in swallowing, difficulties in breathing, facial swelling, severe dizziness with a fast heartbeat and heavy sweating.
- Serious skin reactions such as hives (nettle rash), red sore skin and flaking (dermatitis), blisters, widespread skin peeling, rash, itching, or swelling, particularly around the face and neck. These symptoms may be due to a severe allergic reaction. (Toxic Epidermal Necrolysis, Stevens-Johnson syndrome).
- Severe watery diarrhoea, containing blood and/or mucous (antibiotic associated colitis including pseudomembranous colitis, or bacterial infection of the bowels), which may develop into complications that are life-threatening.
- Lactic acidosis (symptoms may include recurrent nausea or vomiting, abdominal pain or over breathing). Lactic acidosis exists when lactic acid builds up in the bloodstream faster than it can be removed and may be life-threatening.
- Fits or seizures (see **Tell your doctor or healthcare professional before being given LINOACT IV injection**).
- Serotonin syndrome (you may have symptoms like fast heartrate, confusion, abnormal sweating, hallucinations, involuntary movements, chills and shivering). See **Other medicines and LINOACT IV**.

- Problems with your vision such as loss of vision, blurred vision, changes in colour vision, difficulty in seeing detail, or if your field of vision becomes restricted.
- Transient ischaemic attacks (“mini-stroke”, with signs like temporary disturbance of blood flow to the brain causing short term symptoms such as loss of vision, leg and arm weakness, slurring of speech and loss of consciousness).
- Kidney failure, excessive or abnormally large production of urine.

If you have these symptoms, your doctor may stop giving you LINOACT IV and treat you suitably.

Tell your healthcare provider if you notice any of the following:

Frequent side effects

- Fungal infections, especially vaginal or oral “thrush”.
- Difficulty in sleeping.
- Headache, dizziness.
- Metallic taste in the mouth.
- Nausea (feeling sick), vomiting (being sick), abdominal pains, diarrhoea (loose bowels).
- Changes in some blood test results including those measuring your kidney or liver function or blood sugar levels.

Less frequent side effects

- Reversible anaemia (low red blood cells).
- High blood pressure.
- Inflammation of the vagina or genital area in women.

- Changes in numbers of certain cells in the blood which may affect your ability to fight infection.
- Unexplained bleeding or bruising, which may be due to changes in the numbers of certain cells in the blood which may affect blood clotting.
- Skin rash, itching.
- Pain at the injection site, fever.
- Sensations such as tingling or numbness of fingers and toes.
- Convulsions ("fits").
- Blurred vision, field of vision becomes restricted.
- "Ringing" in the ears (tinnitus).
- Changes in heartrate (quicker heartrate).
- Inflammation of the veins, low blood pressure.
- Indigestion, stomach pain, constipation, distended belly, increased thirst, loose stools.
- Dry or sore mouth, swollen, sore, or discoloured tongue.
- Sweating, red inflamed skin.
- Superficial tooth discolouration.

Side effects occurring at unknown frequency:

- Hair loss

- Changes in colour vision, difficulty in seeing detail, loss of vision, optic neuritis (inflammation in optic nerve causing pain with eye movement).

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, pharmacist or nurse. 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 LINOACT IV.

5. How to store LINOACT IV

Store all medicines out of reach of children.

Store at room temperature, at or below 25 °C. Do not freeze. Protect from light – the infusion bags must be kept in their foil overpouch, until ready to use. The infusion bags are only intended for single-use. Discard any unused solution.

Your healthcare provider will check that the LINOACT IV is not past its expiry date stated on the label and carton before giving you the injection.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What LINOACT IV contains

- The active substance is linezolid. Each 300 ml infusion bag of LINOACT IV contains 600 mg linezolid; providing 2 mg linezolid per ml.
- The other ingredients are glucose monohydrate, sodium citrate, citric acid anhydrous, hydrochloric acid, sodium hydroxide and water for injections.

What LINOACT IV looks like and contents of the pack

LINOACT IV is a solution for infusion.

A clear, colourless to yellowish solution, free from visible particles.

LINOACT IV is packaged in a single-use plastic container-closure system (infusion bag) which consists of the following components and materials:

- One multi-layer co-extruded polyolefin plastic bag of 300 ml;
- One multi-layer co-extruded polyolefin plastic port tube;
- One gamma sterilised polyolefin twist-off connector.

Each single-dose infusion bag is imprinted with a hot stamp foil and sealed into a foil overpouch (secondary packaging).

Each bag contains 300 ml solution (600 mg linezolid) and is packaged in a carton box containing 1 or 10 bags.

Not all pack sizes may necessarily be marketed at one time.

Holder of Certificate of Registration

Astral Pharma (Pty) Ltd

49 Riboville Road

Randjiesfontein

Midrand, 1683

South Africa

Tel: +27 (0)82 575 6121

This leaflet was last revised in

21 November 2023

Registration number

Linobact IV: 56/20.1.1/0637