

PROFESSIONAL INFORMATION

SCHEDULING STATUS S4

1. NAME OF THE MEDICINE

LINEOBACT® IV, 600 mg/300 ml solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 300 ml infusion bag of LINEOBACT IV contains 600 mg linezolid; providing 2 mg linezolid per ml.

Excipients with known effect

Contains sugar (15,072 g glucose monohydrate per 300 ml solution).
Contains sodium (131,49 mg sodium per 300 ml solution).
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion.
A clear, colourless to yellowish solution, free from visible particles.
pH range 4,6 – 5,0

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LINEOBACT IV is indicated for the treatment of patients with the following infections, caused by susceptible strains of the designated microorganisms. LINEOBACT IV is not indicated for the treatment of Gram-negative infections. It is critical that specific Gram-negative therapy must be initiated immediately if a concomitant Gram-negative pathogen is documented or suspected (see section 4.4).

Vancomycin-resistant *Enterococcus faecium* infections, including cases with concurrent bacteraemia. A

Nosocomial pneumonia caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant strains), or

Streptococcus pneumoniae (including multi-medicine resistant *S. pneumoniae* (MORSP) strains).

Complicated skin and skin structure infections caused by *Staphylococcus aureus* (methicillin-susceptible and methicillin-resistant strains), *Streptococcus pyogenes*, or *Streptococcus agalactiae*. LINEOBACT IV has not been studied in the treatment of decubitus ulcers.

Uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant strains), *Streptococcus pyogenes*.

Community-acquired pneumonia caused by *Streptococcus pneumoniae* (including multi-medicine resistant *S. pneumoniae* (MORSP) strains), including cases with concurrent bacteraemia, or *Staphylococcus aureus* (methicillin-susceptible and -resistant strains).

Due to concern about inappropriate use of antibiotics leading to an increase in resistant organisms, prescribers should carefully consider alternatives before initiating treatment with LINEOBACT IV in the outpatient setting. Appropriate specimens for bacteriological examination should be obtained in order to isolate and identify the causative organisms and to determine their susceptibility to linezolid. Therapy may be instituted empirically while awaiting results of these tests. Once these results become available, antimicrobial therapy should be adjusted accordingly.

4.2 Posology and method of administration

Posology

Patients who commence treatment on the parenteral formulation should be switched to an oral presentation when clinically indicated.

LINEOBACT IV solution for infusion should be administered over a period of 30 to 120 minutes. The recommended intravenous (IV) dosage schedule for LINEOBACT IV is as follows:

Adult and adolescent (12 years and older) patients:

Infections (including those associated with concurrent bacteraemia)	Dosage and route of administration	Duration of treatment
Community-acquired pneumonia, including concurrent bacteraemia	600 mg IV every 12 hours	10 – 14 consecutive days
Nosocomial pneumonia, including concurrent bacteraemia		
Skin and soft tissue infections, including concurrent bacteraemia	600 mg IV every 12 hours depending on clinical severity	
Enterococcal infections, including vancomycin-resistant infections, and those with concurrent bacteraemia	600 mg IV every 12 hours	14 – 28 consecutive days

Special populations

Paediatric patients (birth* through to 11 years):

Infections (including those associated with concurrent bacteraemia)	Dosage and route of administration	Duration of treatment
Community-acquired pneumonia, including concurrent bacteraemia	10 mg/kg IV every 8 hours	10 – 14 consecutive days
Nosocomial pneumonia, including concurrent bacteraemia		
Skin and soft tissue infections, including concurrent bacteraemia		
Enterococcal infections, including vancomycin-resistant infections, and those with concurrent bacteraemia	10 mg/kg IV every 8 hours	14 – 28 consecutive days

* Pre-term neonates less than 7 days of age (gestational age less than 34 weeks) have lower systemic LINEOBACT IV clearance values and larger AUC values than many full-term neonates and older infants. By day 7 of age, LINEOBACT IV clearance and AUC values are like those of full-term neonates and older infants.

Elderly patients:

No dose adjustment is necessary.

Patients with renal impairment:

- *Patients with renal insufficiency:* No dosage adjustment is required.
- *Patients with severe renal insufficiency* ($CL_{CR} < 30$ ml/min.): No dose adjustment is required. Due to the unknown clinical significance of higher exposure (up to 10-fold) to the two primary metabolites of LINEOBACT IV in patients with severe renal insufficiency, LINEOBACT IV should be used with special caution in these patients and only when the anticipated benefit is considered to outweigh the theoretical risk.

Haemodialysis:

As about 30 % of a LINEOBACT IV dose is removed during 3 hours of haemodialysis. LINEOBACT IV should be given after dialysis in patients receiving such treatment. The primary metabolites of LINEOBACT IV are removed to some extent by haemodialysis, but the concentrations of these metabolites are still considerably higher following dialysis than those observed in patients with normal renal function or mild to moderate renal insufficiency. Therefore LINEOBACT IV should be used with special caution in patients with severe renal insufficiency who are undergoing dialysis and only when the anticipated benefit is considered to outweigh the theoretical risk. There is no experience of LINEOBACT IV administration to patients undergoing continuous ambulatory peritoneal dialysis (CAPD) or alternative treatments for renal failure (other than haemodialysis).

Patients with hepatic insufficiency:

No dose adjustment is required. However, there are limited clinical data and it is recommended that LINEOBACT IV should be used in such patients only when the anticipated benefit is considered to outweigh the theoretical risk.

Method of administration

LINEOBACT IV should be administered intravenously twelve-hourly.

Route of administration: Intravenous use.

Administer LINEOBACT IV solution for infusion over a period of 30 to 120 minutes. See section 6.6 for special precautions on handling.

4.3 Contraindications

LINEOBACT IV is contraindicated for use in patients who have known hypersensitivity to linezolid or any excipients in LINEOBACT IV, listed in section 6.1.

Monoamine oxidase inhibitors

LINEOBACT IV should not be used in patients taking any medicine which inhibits monoamine oxidases A or B (e.g. phenelzine, isocarboxazid), or within two weeks of taking any such medicine.

Relative contraindications:

Potential interactions producing elevation of blood pressure

Unless patients are monitored for potential increases in blood pressure, LINEOBACT IV should not be administered to patients with uncontrolled hypertension, pheochromocytoma, hyperthyroidism and/or patients taking any of the following types of medicines: directly and indirectly acting sympathomimetic medicines (e.g., pseudoephedrine, phenylpropanolamine), vasopressive medicines (e.g., epinephrine, norepinephrine), dopaminergic medicines (e.g., dopamine, dobutamine) (see section 4.5).

Potential serotonergic interactions

Unless patients are carefully observed for signs and/or symptoms of serotonin syndrome, LINEOBACT IV should not be administered to patients with carcinoid syndrome and/or patients taking any of the following medicines: serotonin reuptake inhibitors, tricyclic antidepressants, serotonin 5-HT₁ receptor agonists (triptans), meperidine, pethidine or buspirone (see section 4.5).

4.4 Special warnings and precautions for use

Prescribers should adhere to the principles of antibiotic stewardship.

Pseudomembranous colitis, *Clostridium difficile* associated diarrhoea (CDAD)

Pseudomembranous colitis has been reported with linezolid as in LINEOBACT IV and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea subsequent to the administration of LINEOBACT IV. CDAD has been reported with linezolid as in LINEOBACT IV and may range in severity from mild diarrhoea to fatal colitis. Treatment with LINEOBACT IV alters the normal flora of the colon leading to overgrowth of *Clostridium difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin-producing strains of *C. difficile* cause increased morbidity and mortality as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD should be considered in all patients who present with diarrhoea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial medicines.

Myelosuppression

Reversible myelosuppression (including anaemia, leukopenia, pancytopenia and thrombocytopenia) that may be dependent on duration of therapy has been reported in some patients receiving linezolid (as in LINEOBACT IV). Monitoring of complete blood counts should be considered for patients who are at increased risk for bleeding, who have pre-existing myelosuppression, who receive concomitant medicines that may decrease haemoglobin levels or platelet count or function, or who receive LINEOBACT IV for more than 2 weeks. If significant myelosuppression occurs during LINEOBACT IV therapy, treatment should be stopped unless it is considered absolutely necessary to continue therapy. Cases of sideroblastic anaemia have been reported (see section 4.8). Where time of onset was known, most patients had received linezolid therapy for more than 28 days. Most patients fully or partially recovered following discontinuation of linezolid with or without treatment for their anaemia.

Peripheral and optic neuropathy

Peripheral neuropathy, optic neuropathy and optic neuritis have been reported in patients treated with linezolid (as in LINEOBACT IV). In cases of optic neuropathy that progressed to loss of vision, patients were treated for extended periods beyond the maximum recommended duration. Visual blurring has been reported in some patients treated with linezolid for less than 28 days.

If symptoms of visual impairment appear, such as changes in visual acuity, changes in colour vision, blurred vision, or visual field defect, prompt ophthalmic evaluation is recommended. Visual function should be monitored in all patients receiving LINEOBACT IV for extended periods (≥ 3 months) and in all patients reporting new visual symptoms regardless of length of therapy with LINEOBACT IV. If peripheral or optic neuropathy occurs, the continued use of LINEOBACT IV in these patients should be weighed against the potential risks. There may be an increased risk of neuropathies when LINEOBACT IV is used in patients currently taking or who have recently taken antimycobacterial medicines for the treatment of tuberculosis.

Lactic acidosis

Lactic acidosis has been reported with the use of linezolid as in LINEOBACT IV. Patients who develop recurrent nausea or vomiting, unexplained acidosis, or a low bicarbonate level while receiving LINEOBACT IV should receive immediate medical attention.

Mitochondrial dysfunction

Linezolid, contained in LINEOBACT IV, inhibits mitochondrial protein synthesis. Adverse events, such as lactic acidosis, anaemia and neuropathy (optic and peripheral), may occur as a result of this inhibition; these events are more common when LINEOBACT IV is used longer than 28 days.

Convulsions

Convulsions have been reported in patients treated with linezolid as in LINEOBACT IV (see section 4.8). In some of these cases a history of seizures or risk factors for seizures were reported.

Gram-negative pathogens

LINEOBACT IV has no clinical activity against Gram-negative pathogens and is not indicated for the treatment of Gram-negative infections (see sections 5.1 and 4.1). Specific Gram-negative therapy is required if a concomitant Gram-negative pathogen is documented or suspected.

LINEOBACT IV should be used with special caution in patients at high risk for life-threatening systemic infections, such as those with infections related to central venous catheters in intensive care units. LINEOBACT IV is **not** approved for the treatment of patients with catheter-related bloodstream infections.

Superinfection

The use of antibiotics (including LINEOBACT IV) may result in an overgrowth of non-susceptible organisms. Should superinfection occur during therapy, appropriate treatment should be instituted.

Treatment period

The safety and efficacy of LINEOBACT IV when administered for periods longer than 28 days have not been established.

Serotonin syndrome

Spontaneous reports of serotonin syndrome associated with the co-administration of linezolid as in LINEOBACT IV and serotonergic medicines, including antidepressants such as selective serotonin reuptake inhibitors (SSRIs) have been reported. Co-administration of LINEOBACT IV and serotonergic medicines is therefore contraindicated (see section 4.3), except where administration of LINEOBACT IV and concomitant serotonergic medicines is essential. In those cases, patients should be closely observed for signs and symptoms of serotonin syndrome such as cognitive dysfunction, hyperreflexia, hyperreflexia and incoordination. If signs or symptoms occur, medical practitioners should consider discontinuing either one or both medicines; if the concomitant serotonergic medicine is withdrawn, discontinuation symptoms can occur.

Patient populations

Underlying clinical conditions

LINEOBACT IV has not been studied in patients with uncontrolled hypertension, phaeochromocytoma, carcinoid syndrome or untreated hyperthyroidism.

Renal impairment

LINEOBACT IV should be used with special care in patients with severe renal impairment and only when the expected benefit is considered to exceed the theoretical risk.

Hepatic impairment

It is recommended that LINEOBACT IV should be used in patients with severe hepatic insufficiency only when the anticipated benefit is considered to outweigh the theoretical risk.

Excipients with known effect

LINEOBACT IV contains 50,24 mg/ml glucose monohydrate (15,072 g per 300 ml solution). This should be taken into account in patients with diabetes mellitus or other conditions associated with glucose intolerance.

LINEOBACT IV contains 0,44 mg sodium/ml (131,49 mg sodium per 300 ml solution), equivalent to 6,6 % of the recommended maximum daily intake of 2 g sodium for an adult, per 300 ml bag.

4.5 Interactions

Unless there are facilities available for close observation and monitoring of blood pressure, LINEOBACT IV should not be administered to patients taking serotonin reuptake inhibitors, tricyclic antidepressants, serotonin 5-HT₁ receptor agonists (triptans), directly and indirectly acting sympathomimetic medicines (including the adrenergic bronchodilators, pseudoephedrine and phenylpropanolamine), vasopressive medicines (e.g. epinephrine, norepinephrine), dopaminergic medicines (e.g. dopamine, dobutamine), meperidine, pethidine or buspirone (see section 4.3 and 4.4).

Monoamine oxidase inhibitors and medicines producing elevation of blood pressure

LINEOBACT IV is a reversible, non-selective inhibitor of monoamine oxidase (MAO); it is contraindicated in patients treated with monoamine oxidase inhibitors or within two weeks of taking such a medicine (see section 4.3). LINEOBACT IV produces a mild, reversible enhancement of the pressor responses induced by pseudoephedrine and phenylpropanolamine hydrochloride. Thus, the potential for interaction with sympathomimetic or adrenergic medicines should be considered and doses of compounds, such as dopamine or epinephrine (adrenalin), should be titrated to achieve the desired response.

Serotonergic interactions

Serotonin syndrome, associated with the simultaneous administration of LINEOBACT IV and serotonergic medicines, including antidepressants such as SSRIs, has been reported (see section 4.3 and 4.4). Although LINEOBACT IV has the potential for interaction with serotonergic medicines, no serotonin effects were observed in patients receiving linezolid and dextromethorphan.

Where administration of LINEOBACT IV and concomitant serotonergic medicines is clinically appropriate, patients should be closely observed for signs and symptoms of serotonin syndrome such as cognitive dysfunction, hyperreflexia, hyperreflexia and incoordination. If signs or symptoms occur medical practitioners should consider discontinuation of either one or both medicines. If the concomitant serotonergic medicine is withdrawn, discontinuation symptoms can be observed.

Tyramine-rich foods

No significant pressor response was observed in patients receiving both linezolid and 100 mg tyramine. This suggests that it is only necessary to avoid ingesting excessive amounts of food and beverages with high tyramine content (e.g. mature cheese, yeast extracts, undistilled alcoholic beverages and fermented soybean products such as soy sauce), to prevent a pressor response.

Cytochrome P450 interactions

LINEOBACT IV is not detectably metabolised by the cytochrome P450 (CYP) enzyme system and it does not induce or inhibit the activities of clinically significant human CYP isoforms (1A2, 2C9, 2C19, 2D6, 2E1, 3A4). Therefore, no CYP450-induced medicine interactions are expected with LINEOBACT IV. No interactions have been reported in pharmacokinetic studies with either aztreonam or gentamicin.

Warfarin

When warfarin was added to linezolid therapy at steady-state, there was a 10 % reduction in mean maximum international normalised ratio (INR) on co-administration with a 5 % reduction in AUC INR. There are insufficient data from patients who have received warfarin and linezolid (such as LINEOBACT IV) to assess the clinical significance, if any, of these findings.

Rifampicin

Concomitant administration of rifampicin with LINEOBACT IV may cause a decrease of about 20 % in linezolid C_{max} and a decrease of about 30 % in linezolid AUC. The mechanism of this interaction and the clinical significance thereof is unknown.

4.6 Fertility, pregnancy and lactation

The use of LINEOBACT IV intravenous solution in pregnancy and lactation is contraindicated, as safety has not been demonstrated.

Pregnancy

Studies in animals have shown reproductive toxicity; a potential risk for humans exists.

Breastfeeding

LINEOBACT IV may be secreted into breast milk. Breastfeeding should therefore be discontinued prior to and throughout administration.

Fertility

Linezolid, as in LINEOBACT IV, caused a reduction in fertility in animals. The possible effect on the human male reproductive system has not been established.

4.7 Effects on ability to drive and use machines

Patients should be informed not to drive or handle machinery or tools if they experience dizziness or visual impairment (see section 4.8).

4.8 Undesirable effects

Summary of the safety profile

Frequently reported adverse reactions are headache, diarrhoea, nausea, vomiting, metallic taste, abnormal liver function tests and vaginal moniliasis.

The most frequently reported medicine-related adverse events which led to discontinuation of treatment were headache, diarrhoea, nausea and vomiting.

Tabulated summary of adverse reactions

Infections and infestations:

Frequent: Oral and vaginal candidiasis, fungal infections.

Less frequent: Vaginitis, antibiotic-associated colitis, *Clostridium difficile* associated diarrhoea (CDAD), pseudomembranous colitis (may be fatal; see section 4.4)

Blood and the lymphatic system disorders:

Less frequent: Reversible anaemia, leukopenia, neutropenia, thrombocytopenia, eosinophilia, pancytopenia (see section 4.4)

Frequency unknown:

Myelosuppression, sideroblastic anaemia (see section 4.4).

Immune system disorders:

Less frequent: Anaphylaxis, angioedema.

Metabolism and nutrition disorders:

Less frequent: Hyponatraemia, increased serum creatine phosphokinase, hyperglycaemia, lactic acidosis (see section 4.4).

Psychiatric disorders:

Frequent: Insomnia.

Nervous system disorders:

Frequent: Headache, taste perversion (metallic taste), dizziness.

Less frequent: Convulsions (see section 4.4), hypoaesthesia, paraesthesia, serotonin syndrome (see sections 4.3 and 4.5), peripheral neuropathy (see section 4.4).

Eye disorders:

Less frequent: Blurred vision, changes in visual field defect (see section 4.4).

Frequency unknown: Optic neuropathy, optic neuritis, loss of vision, changes in visual acuity, changes in colour vision (see section 4.4).

Ear and labyrinth disorders:

Less frequent: Tinnitus

Cardiac disorders:

Less frequent: Dysrhythmia (tachycardia).

Vascular disorders:

Less frequent: Transient ischaemic attacks, phlebitis, thrombophlebitis, hypertension, hypotension.

Gastrointestinal disorders:

Frequent: Diarrhoea, nausea, vomiting, localised or general abdominal pain.

Less frequent: Pancreatitis, gastritis, abdominal distention, dry mouth, glossitis, loose stools, stomatitis, tongue discoloration or disorder, constipation, dyspepsia, increased thirst, superficial tooth discoloration.

Hepatobiliary disorders:

Frequent: Abnormal liver function tests; increased AST, ALT or alkaline phosphatase.

Less frequent: Increased total bilirubin.

Skin and subcutaneous tissue disorders:

Less frequent: Pruritus, rash, urticaria, dermatitis, diaphoresis. Bullous skin disorders such as Stevens-Johnson syndrome and toxic epidermal necrolysis.

Frequency unknown:

Alopecia.

Renal and urinary disorders:

Frequent: Increased BUN (blood urea)

Less frequent: Renal failure, increased creatinine, polyuria.

Reproductive system and breast disorders:

Less frequent: Vulvovaginal disorder.

General disorders and administration site conditions:

Less frequent: Fever, localised pain, chills, fatigue, injection site pain.

Investigations:

Frequent:

Chemistry: Increased lactate dehydrogenase (LDH), creatine kinase, lipase, amylase or non-fasting glucose. Decreased total protein, albumin, sodium or calcium. Increased or decreased potassium or bicarbonate.

Haematology: Increased neutrophils or eosinophils. Decreased haemoglobin, haematocrit or red blood cell count. Increased or decreased platelet or white blood cell counts.

Chemistry: Increased sodium or calcium. Decreased non-fasting glucose. Increased or decreased chloride.

Haematology: Increased reticulocyte count, decreased neutrophils.

Less frequent:

Chemistry: Increased sodium or calcium. Decreased non-fasting glucose. Increased or decreased chloride.

Haematology: Increased reticulocyte count, decreased neutrophils.

Description of selected adverse reactions

The following adverse reactions to linezolid (as in LINEOBACT IV) were considered to be serious in rare cases: localised abdominal pain, transient ischaemic attacks and hypertension.

Paediatric population

Safety data do not indicate that the safety profile of linezolid for paediatric patients differs from that for adult patients.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity, see section 4.8. Supportive care is advised together with maintenance of glomerular filtration. Approximately 30 % of a LINEOBACT IV dose is removed during 3 hours of haemodialysis, but no data are available for the removal of LINEOBACT IV by peritoneal dialysis or haemoperfusion.

5. PHARMACOLOGICAL ACTION

5.1 Pharmacodynamic properties

A 20.1.1 Broad and medium spectrum antibiotics

Pharmacotherapeutic group: Other antibacterial, ATC code: J 01 X X 08

Mechanism of action

Linezolid is a synthetic antibiotic that belongs to the oxazolidinone class of antibiotics. It has *in vitro* activity against aerobic Gram-positive bacteria and anaerobic microorganisms. Linezolid selectively inhibits bacterial protein synthesis through binding to sites on the bacterial ribosome and prevents the formation of a functional 70S-initiation complex, which is a necessary component of the translation process. Linezolid is not active against Gram-negative pathogens (see section 4.1).

Resistance:

Linezolid’s mechanism of action differs from that of other antibiotics, e.g. the aminoglycosides, beta-lactams, folic acid antagonists, glycopeptides, lincosamides, quinolones, rifamycins, streptogramins, tetracyclines and chloramphenicol. Therefore, cross-resistance between linezolid and these classes of medicines is not expected. *In vitro* studies showed that resistance to linezolid develops slowly via multiple step mutations in 23S ribosomal RNA and occurs at frequencies of less than 1 x 10⁻⁸ to 1 x 10⁻¹⁰.

Resistant organisms:

Haemophilus influenzae

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LINOBACT® 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 LINOBACT 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

- What LINOBACT IV is and what it is used for
- What you need to know before LINOBACT IV is administered to you
- How LINOBACT IV will be administered to you
- Possible side effects
- How to store LINOBACT IV
- Contents of the pack and other information

1. What LINOBACT IV is and what it is used for
Linezolid is an antibiotic of the oxazolidinone group, that works by stopping the growth of certain bacteria (germs) that cause infections.

LINOBACT 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 LINOBACT IV is suitable to be used for the type of infection you have.

2. What you need to know before LINOBACT IV is administered to you
LINOBACT IV should not be administered to you:

- if you are hypersensitive (allergic) to linezolid or any of the other ingredients of LINOBACT 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.
- LINOBACT 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 LINOBACT IV.

Tell your doctor or healthcare provider before being given LINOBACT IV:

- if you already have loose bowels or have recently been treated with an antibiotic medicine. LINOBACT 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 LINOBACT IV may worsen the condition;
- if you tend to get infections, as LINOBACT IV may cause a decrease in white blood cells;
- if you bruise or bleed easily, as LINOBACT IV may cause a decrease in platelets;
- if you have a history of seizures ("fits"), as convulsions have been reported during treatment with LINOBACT IV;
- if you have liver or kidney problems (especially if you have dialysis);

You should also know that:

- LINOBACT 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 LINOBACT IV. If this becomes severe or persistent or you notice that your stool contains blood or mucus, treatment with LINOBACT 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 LINOBACT 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**.
- LINOBACT 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 LINOBACT IV**.

Other medicines and LINOBACT IV

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

- You should not receive LINOBACT IV if you are currently taking or have taken MAOIs within the last 14 days (for example phenelzine, isocarboxamid, selegiline, moclobemide). These may be used to treat depression or Parkinson's disease. See **LINOBACT IV 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.

LINOBACT 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 LINOBACT 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 LINOBACT IV.

The effect of LINOBACT IV in pregnant women is not known; it should therefore not be used during pregnancy. Reproductive toxicity was demonstrated in animals. Linezolid (contained in LINOBACT 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 LINOBACT IV because it passes into breast milk and could affect the baby.

Driving and using machines

LINOBACT 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 LINOBACT IV could interfere with your ability to drive safely.

LINOBACT IV contains glucose and sodium

Glucose

Each 1 ml of LINOBACT 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 LINOBACT IV.

Sodium

Each 1 ml of LINOBACT 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 LINOBACT IV will be administered to you

You will not be expected to give yourself LINOBACT IV. It will be given to you by a person who is qualified to do so. LINOBACT IV is normally administered in hospital. Your doctor will tell you how long your treatment with LINOBACT 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 LINOBACT IV**).

The usual dose is:

- Adults:** LINOBACT 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 LINOBACT 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 LINOBACT IV dose after the dialysis procedure. If you have the impression that the effect of LINOBACT IV is too strong or too weak, tell your doctor or pharmacist.

If you receive more LINOBACT IV than you should

Since a healthcare provider will administer LINOBACT IV, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose. Tell your doctor or healthcare provider at once if you think you may have been given too much LINOBACT IV.

If you missed a dose of LINOBACT IV

Since a healthcare provide will administer LINOBACT 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 LINOBACT IV

To clear up your infection completely, LINOBACT 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 LINOBACT IV.

4. Possible side effects

LINOBACT IV can have side effects.

Not all side effects reported for LINOBACT IV are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving LINOBACT IV, please consult your healthcare provider for advice. LINOBACT 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 mucus (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 LINOBACT IV**).
- Serotonin syndrome (you may have symptoms like fast heartrate, confusion, abnormal sweating, hallucinations, involuntary movements, chills and shivering). See **Other medicines and LINOBACT 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 LINOBACT 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 notice any 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#. By reporting side effects, you can help provide more information on the safety of LINOBACT IV.

5. How to store LINOBACT IV

Store all medicines out of reach of children. Store LINOBACT IV in its original container, 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 LINOBACT 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 LINOBACT IV contains

- The active substance is linezolid. Each 300 ml infusion bag of LINOBACT 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 LINOBACT IV looks like and contents of the pack

LINOBACT IV is a solution for infusion.

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

LINOBACT 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.

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This leaflet was last revised in

21 November 2023

Registration number

LINOBACT IV: 56/20.1.1/0637

LIN_IV_PIL V1:2024

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

LINOBACT® IV , 600 mg/300 mg oplossing vir infusie Linezolid
Bevat suiker (glukosemonohidraat 50,24 mg/ml oplossing)

Lees die hele inligtingsblad aandagdig deur voordat LINOBACT IV aan jou gegee word

- Hou hierdie inligtingsblad. Dit is moontlik dat jy dit weer sal wil lees.
- Indien jy verdere vrae het, raadpleeg asseblief jou dokter of apteker.

Wat is in hierdie inligtingsblad

- Wat is LINOBACT IV en waarvoor word dit gebruik
- Wat jy moet weet voordat LINOBACT IV aan jou toegedien word
- Hoe LINOBACT IV aan jou toegedien sal word
- Moontlike newe-effekte
- Hoe om LINOBACT IV te bewaar
- Inhoud van die pakkie en ander inligting

1. Wat is LINOBACT IV en waarvoor word dit gebruik

Linezolid is 'n antibiotikum wat die oksasolidinongroep, wat werk deur die groei van bakterieë (kieme) wat infeksies veroorsaak te stop. LINOBACT IV kan deur jou dokter voorgeskryf word om sekere infeksies te behandel, insluitend pneumonie en sommige infeksies in of onder die vel. Jou dokter sal bepaal of LINOBACT IV geskik is vir die tipe infeksie wat jy het.

2. Wat jy moet weet voordat LINOBACT IV aan jou toegedien word

- LINOBACT IV moet nie aan jou toegedien word nie:
 - Indien jy hipersensitief (allergies) is vir linesolied of enige van die ander bestanddele van LINOBACT IV (gelys in afdeling 4).
 - indien jy met monoamienoksidasie-inhibitore behandel word (voorbeeld van monoamienoksidasie-inhibitore (MAOI's) sluit in fenelzine, isokarboxsieluur) of binne 2 weke nadat jy so 'n medisyne geneem het. Hierdie medisyne is moontlik vir depressie of Parkinson se siekte aan jou voorgeskryf.
 - LINOBACT IV is moontlik nie geskik vir jou as jy enige van die volgende mediese toestande het nie. In hierdie geval, stel jou dokter in kennis aangesien hy of sy jou algemene gesondheid en bloeddruk voor en tydens behandeling sal moet kontroleer of dalk sal besluit dat 'n ander behandeling beter vir jou is.
 - Vra jou dokter as jy nie seker is of jy enige van die volgende siekte toestande het nie:
 - Hoë bloeddruk, en watter medisyne jy daarvoor neem
 - 'n Ooraktiewe skildklier
 - 'n Gewas van die biniere (feochromistoom), of karsinoïede sindroom (veroorzaak deur gewasse van die hormoonstelsel met simptome van diarree, bloesende vel, fluitende bors)
 - Indien jy tans enige van die volgende medisyne neem:
 - Ontswingsmiddels of verkoue- of griepmedisyne wat pseudo-efedrien of fenielpropanolamien bevat
 - Medisyne gebruik vir die behandeling van Parkinson se siekte (dopamien)
 - Medisyne gebruik vir die behandeling van hartversaking (dobutamin)
 - Antidepressante bekend as trisikliese middels of SSHI's (selektiewe serotonineropname-inhibitore)
 - Medisyne gebruik vir die behandeling van angs (soos buspiron)
 - Medisyne gebruik vir die behandeling van matige tot ernstige pyn, soos petidien, meperidien.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met LINOBACT IV:

Lig jou dokter of gesondheidsorgverskaffer in van die volgende, voordat LINOBACT IV aan jou gegee word:

- indien jy reeds 'n loopmaag het of onlangs met 'n antibiotiese medisyne behandel is. LINOBACT IV kan inflammasie en infeksie van die ingewande veroorsaak (kyk ***Jy moet ook weet dat;***
- indien jy anemie het (lae rooibloedselting), aangesien LINOBACT IV die sieketoeestand kan vererger;
- indien jy geneig is om infeksies te kry, aangesien LINOBACT IV 'n afname in witbloedselle kan veroorsaak;
- indien jy maklik kneuus of bloet, aangesien LINOBACT IV 'n afname in blootpleetjies kan veroorsaak;
- indien jy 'n geskiedenis het van stuiprekkings ("toevalle"), aangesien stuiprekkings aangemeld is tydens behandeling met LINOBACT IV;
- indien jy lewer- of nierprobleme het (veral as jy dialise ondergaan).

Jy moet ook weet dat:

- LINOBACT IV kan ernstige diarree en infeksie in die derms veroorsaak (kyk afdeling 4, **Moontlike newe-effekte**). Jy kan tydens en na behandeling met LINOBACT IV diarree ontwikkel. Indien dit ernstig of aanhoudend word of jy atermok dat jou stoelgang bloed of slym bevat, moet behandeling met LINOBACT IV onmiddellik gestaak word en jou dokter geraadpleeg word. Moenie medisyne neem wat dermbewegings vertraag of stop nie.
- Hoë vlakke van serotonien ('n chemiese stof in jou liggaam) kom voor wanneer jy ook ander medisyne neem, veral selektiewe serotonineropname-inhibitore (SSHI's) vir depressie (kyk **Ander medisyne en LINOBACT IV**). Lig jou dokter in van al hierdie medisyne en kontak hom/haar dadelik as jy veranderde geestestoestand ervaar, insluitend agitاسie, verwarring, koma, stywe spiere, bewing, swak koördinasie en toevalle.
- Laktasidose kan voorkom: Lig jou dokter in as jy spieryne, brandgevoel, winnige asemhaling, naardeh en maagpyn het. Kyk **Moontlike newe-effekte**.
- LINOBACT IV kan inflammasie van die optiese senewee veroorsaak (kyk **Moontlike newe-effekte**). Lig jou dokter dadelik in as jy probleme met jou visie kry, soos dowwe visie, veranderings in kleurwaarneming, sukkel om detail te sien of as jou gesigsveld beperk raak.
- Perifere neuropatie kan voorkom: Dit is die gevolg van skade aan jou perifere senewees wat swakheid, gevoelloosheid en pyn veroorsaak, gewoonlik in jou hande en voete. Lig jou dokter in as jy medisyne neem vir die behandeling van tuberkulose (TB), want dit kan jou risiko verhoog om hierdie sieketoeestand te ontwikkel. (Kyk **Ander medisyne en LINOBACT IV**).

Ander medisyne en LINOBACT IV
Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

- Jy moet nie LINOBACT IV ontvang as jy tans MAOI's neem of geneem het binne die afgelope 14 dae nie (byvoorbeeld fenelzine, isokarboxsied, selegiline, moklobemied). Hierdie medisyne kan gebruik word vir die behandeling van depressie of Parkinson se siekte. Kyk **LINOBACT IV moet nie aan jou toegedien word nie**.
- Jou dokter kan 'n ander medisyne oorweeg as jy tans die volgende medisyne neem/gebruik, of onlangs gebruik het:
 - Ontswingsmiddels of verkoue- of griepmedisyne wat pseudo-efedrien of fenielpropanolamien bevat
 - Medisyne soos epinefrien (adrenalin) wat gebruik word om skielike, ernstige allergiese reaksies te behandel.
 - Medisyne wat jou bloeddruk verhoog, soos norepinefrien (noradrenalin), dopamien en dobutamien.
 - Sekere antidepressante bekend as trisikliese middels of SSHI's. Daar is baie voorbeelde hiervan, insluitend amitriptiline, klomipramien, fluoksetien, fluvoxamin, imipramien, paroksetien en sertralien.
 - Medisyne gebruik vir die behandeling van angs, soos buspiron.
 - Medisyne gebruik vir die behandeling van matig-tot-ernstige pyn, soos petidien en meperidien.
 - Medisyne wat bloedstolling voorkom, soos warfarin.
 - 'n Antibiotikum vir tery (TB), genaamd rifampisien.

LINOBACT IV met kos en vloeistowwe

Vermý groot hoeveelhede belee kaas, gis-ekstrakte, of sojaboon-ekstrakte, bv. sojasous, en die inname van alkohol, veral vatbier en wyn. Dit is omdat linesolied (soos in LINOBACT IV) kan reageer met 'n stof genaamd tiramen wat natuurlik in sekere kosse voorkom en so 'n verhoging van jou bloeddruk veroorsaak. Indien jy 'n kloppende hoofpyn ontwikkel nadat jy geëet of gedrink het, lig jou dokter of apteker dadelik in.

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of borsvoed, dink jy is dalk swanger, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy LINOBACT IV ontvang.

Die effek van LINOBACT IV in swanger vroue is onbekend, dus moet jy dit nie tydens swangerskap ontvang nie. Reproductiewe toksisiteit is by diere aangetoon. LINOBACT IV (bevat in LINOBACT IV) het vrugbaarheid by diere verminder. Die moontlike effek op die manlike voorplantingstelsel van die mens is nie vasgestel nie. Jy moet nie jou baba borsvoed terwyl jy LINOBACT IV ontvang nie, want dit kom in borsmelk voor en kan jou baba dalk aantas.

Bestuur en die gebruik van masjinerie

LINOBACT IV kan jou duiselig laat voel, of jy kan probleme met jou visie ervaar (kyk **Moontlike newe-effekte**). Moenie bestuur of gereedskap of masjinerie gebruik nie omdat LINOBACT IV jou vermoë om veilig te bestuur kan beïnvloed.

LINOBACT IV bevat glukose en natrium

Glukose

Elke 1 ml LINOBACT IV bevat 50,24 mg glukosemonohidraat (15,072 g glukosemonohidraat in 'n sak met 300 ml oplossing). Dit moet in berekening gebring word by pasiënte met diabetes mellitus. Lig jou dokter in as jy 'n intoleransie vir sommige suikers het, voordat jy LINOBACT IV ontvang.

Natrium

Elke 1 ml LINOBACT IV oplossing bevat 0,44 mg natrium (131,49 mg natrium in 'n sak met 300 ml oplossing). Lig asseblief jou dokter of verpleegster in as jy op 'n lae-natrium dieet is.

3. Hoe LINOBACT IV aan jou toegedien sal word

Daar sal nie van jou verwag word om LINOBACT IV aan jouself toe te dien nie. Dit sal aan jou gegee word deur 'n persoon wat gekwalifiseer is om dit te doen. LINOBACT IV word gewoonlik in 'n hospitaal toegedien. Jou dokter sal jou inlig hoe lank jou behandeling met LINOBACT IV sal aanhou. Moenie die behandeling te vroeg staak nie, want 'n volle kursus antibiotiese behandeling is nodig om die kieme wat jou siek maak uit te roei (kyk **Indien jy behandeling met LINOBACT IV staak**).

Die gewone dosis is:

Volwassenes:

- LINOBACT IV sal ingedrup word in 'n groot aar oor 'n tydperk van 30 tot 120 minute.
- Jou dokter sal jou tipe infeksie en mediese toestand in ag neem wanneer hulle op 'n dosis besluit. Tipiese dosisse is 600 mg elke 12 uur. Die behandeling kan tussen 10 en 28 dae duur, afhankende van jou infeksie en reaksie daarop.

Kinders:

- Die dosis LINOBACT IV hang af van jou kind se liggaamsgewig en hoe erg die infeksie is. Tipiese dosisse is 10 mg/kg elke 8 uur, toegedien deur binnearese indruppeling. Die behandeling kan van 10 tot 28 dae duur, afhankende van jou kind se infeksie en reaksie daarop.

Indien jy hemodialise ontvang, sal jou dokter die LINOBACT IV dosis na die dialiseproses toedien. Indien jy die indruk kry dat die effek van LINOBACT IV te sterk of te swak is, lig jou dokter of apteker in.

Indien jy meer LINOBACT IV ontvang het as wat jy moes



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Date: 26 March 2024
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Customer: Astral
Product Name: Linobact IV PI/PI:
Product Code: LIN_PI VI:2024
LIN_PIL VI:2024
Dimensions: 297 x 420 mm
Fold Size: 38 x 90 mm
Font Size: 6 point Helvetica
Colours: (1) Black
--
Pharmacode: --
Stock: 40 gsm
Proof Status: 4th (Fourth)

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