

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

LINEZOLID 600 mg/300 ml ASPEN solution for infusion Linezolid

Contains sugar: Glucose monohydrate 50,24 mg/ml

Each ml contains 0,38 mg (114 mg/300 ml) sodium

Read all of this leaflet carefully before you are given LINEZOLID 600 mg/300 ml ASPEN

- 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 LINEZOLID 600 mg/300 ml ASPEN is and what it is used for
2. What you need to know before you are given LINEZOLID 600 mg/300 ml ASPEN
3. How to be given LINEZOLID 600 mg/300 ml ASPEN
4. Possible side effects
5. How to store LINEZOLID 600 mg/300 ml ASPEN
6. Contents of the pack and other information

1. What LINEZOLID 600 mg/300 ml ASPEN is and what it is used for

LINEZOLID 600 mg/300 ml ASPEN is an antibiotic of the oxazolidinones group that works by stopping the growth of certain bacteria (germs) that cause infections. It is used to treat pneumonia and some infections in the skin or under the skin. Your doctor will have decided if LINEZOLID 600 mg/300 ml ASPEN is suitable to treat your infection.

2. What you need to know before are given LINEZOLID 600 mg/300 ml ASPEN

LINEZOLID 600 mg/300 ml ASPEN should not be administered to you:

- if you are hypersensitive (allergic) to linezolid or any of the other ingredients of LINEZOLID 600 mg/300 ml ASPEN (listed in section 6).
- if you are taking or have taken within the last 2 weeks any medicines known as monoamine oxidase inhibitors (MAOI's for example, phenelzine, isocarboxazid, selegiline, moclobemide). These medications may be used to treat depression or Parkinson's disease.
- if you have high or uncontrolled blood pressure as there are potential interactions, producing elevation of blood pressure.
- if you have been diagnosed with an overactive thyroid.
- if you have 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 use any serotonin re-uptake inhibitors (e.g. citalopram, fluoxetine), tricyclic antidepressants (e.g. amitriptyline, imipramine), meperidine or buspirone for conditions such as manic depression, schizoaffective disorder, mental confusion, other mental problems,
- serotonin 5-HT₁ receptor agonists, medicines used to treat migraines such as triptans, sumatriptan

(as these may cause potential serotonergic interactions, and you will need to be observed for signs and symptoms of serotonin syndrome such as agitation, confusion, rapid heart rate and blood pressure).

Warnings and precautions

Take special care with LINEZOLID 600 mg/300 ml ASPEN

Tell your doctor before you are given this medicine if you:

- have a history of seizures
- have liver problems
- have kidney problems particularly if you are on dialysis
- have diarrhoea
- if you suffer from any uncontrolled or untreated high blood pressure, tumour of the adrenal gland tissue (it results in the release of too much epinephrine and norepinephrine, hormones that control heart rate metabolism and blood pressure)
- bruise and bleed easily, are anaemic (have low red blood cells), are prone to getting infections as these may be due to myelosuppression (condition in which bone marrow activity is decreased, resulting in fewer red blood cells, white blood cells, and platelets)

Tell your doctor immediately if during treatment you suffer from:

- gradual onset of numbness, prickling or tingling in your feet or hands, which can spread upward into your legs and arms, sharp, jabbing, throbbing or burning pain, extreme sensitivity to touch as these may be signs of peripheral neuropathy which refers to the conditions that result when nerves that carry messages to and from the brain and spinal cord from and to the rest of the body are damaged or diseased.
- pain when you move your eyes, blurred or loss of colour vision, trouble seeing to the side, a hole in the centre of your vision, blindness, dull headache between your eyes, as this may be optical neuropathy which is possible damage to the optic nerve from any cause.
- if you feel exhaustion, extreme fatigue, muscle cramps or pain, body weakness. Diarrhoea, decrease in appetite, headache, vomiting, abdominal pain or rapid breathing as you may be experiencing lactic acidosis which is a form of metabolic

acidosis that begins when a person overproduces and underutilises lactic acid and their body is not able to adjust to these changes

- if you experience any fitting (convulsions).
- if you experience agitation or restlessness, confusion, rapid heart rate and high blood pressure, dilated pupils, loss of muscle coordination or twitching muscles, muscle rigidity, heavy sweating or diarrhoea as these may be symptoms of serotonin syndrome which is a group of symptoms that may occur with the use of certain serotonergic medicines.
- if you develop diarrhoea while taking or after taking antibiotics, including LINEZOLID 600 mg/300 ml ASPEN. If this becomes severe or persistent or you notice that your stool contains blood or mucus, you should stop taking LINEZOLID 600 mg/300 ml ASPEN immediately and consult your doctor. In this situation, you should not take medicines that stop or slow bowel movement (this may be associated with pseudomembranous colitis which refers to swelling or inflammation of the large intestine (colon) due to an overgrowth of *Clostridium difficile* (*C difficile*) bacteria. This infection is a common cause of diarrhoea after antibiotic use).

Other medicines and LINEZOLID 600 mg/300 ml ASPEN

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

There is a risk that LINEZOLID 600 mg/300 ml ASPEN may sometimes interact with certain other medicines to cause side effects such as changes in blood pressure, temperature or heart rate.

Tell your doctor if you are taking or have taken within the last 2 weeks the following medicines, as LINEZOLID 600 mg/300 ml ASPEN must not be taken if you are already taking these medicines or have taken them recently (see also Section 2 above, LINEZOLID 600 mg/300 ml ASPEN should not be administered to you).

- monoamine oxidase inhibitors (MAOIs) for example phenelzine, isocarboxazid, selegiline, moclobemide). These may be used to treat depression or Parkinson's disease.

Also tell your doctor if you are taking the following medicines. Your doctor may still decide to give you LINEZOLID 600 mg/300 ml ASPEN but will need to check your general health and your blood pressure before and during your treatment. In other cases, your doctor may decide that another treatment is better for you.

- Decongestant cold or flu remedies containing pseudoephedrine or phenylpropanolamine.
- Certain antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors). There are many of these, including amitriptyline, citalopram, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine, sertraline.
- Medicines used to treat migraine such as sumatriptan and zolmitriptan.
- Medicines used to treat sudden, severe allergic reactions such as adrenaline (epinephrine).
- Medicines which increase your blood pressure, such as noradrenaline (norepinephrine), dopamine and dobutamine.
- Medicines used to treat moderate to severe pain, such as pethidine.
- Medicines used to treat anxiety disorders, such as buspirone.
- An antibiotic called rifampicin use to treat tuberculosis and other infections.

LINEZOLID 600 mg/300 ml ASPEN with food and drink and alcohol

- You can receive LINEZOLID 600 mg/300 ml ASPEN either before, during or after a meal.
- 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 600 mg/300 ml ASPEN may react with a substance called tyramine which is naturally present in some foods. This interaction may cause an increase in your blood pressure.
- If you develop a throbbing headache after eating or drinking, tell your doctor, pharmacist or nurse immediately.

Pregnancy and breastfeeding

You should not use LINEZOLID 600 mg/300 ml ASPEN if you are pregnant or breastfeeding your baby.

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 taking this medicine.

Driving and using machines

LINEZOLID 600 mg/300 ml ASPEN may cause dizziness or changes in the way you see (visual impairment), thus it may have a moderate influence on your ability to drive, use machinery or perform any tasks that require concentration.

It is not always possible to predict to what extent LINEZOLID 600 mg/300 ml ASPEN may interfere with the daily activities of a patient. This medicine will be administered to you in hospital. Patients should ensure that they do not engage in the above activities until they are

aware of the measure to which LINEZOLID 600 mg/300 ml ASPEN affects them (see section 4).

LINEZOLID 600 mg/300 ml ASPEN contains 50,24 mg/ml of glucose monohydrate.

This should be considered if you have diabetes mellitus.

LINEZOLID 600 mg/300 ml ASPEN contains sodium

This medicine contains 114 mg sodium (main component of cooking/table salt) in each 300 ml bag. This is equivalent to 5,7 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to be given LINEZOLID 600 mg/300 ml ASPEN

You will not be expected to give yourself LINEZOLID 600 mg/300 ml ASPEN. It will be given to you by a person who is qualified to do so.

Adults

LINEZOLID 600 mg/300 ml ASPEN will be given to you through a drip (by infusion into a vein) by a doctor or healthcare professional. The recommended dose for adults (18 years and older) is 300 ml (600 mg linezolid) twice daily which is given directly into the blood stream (intravenously) by a drip over a period of 30 to 120 minutes.

If you are on kidney dialysis, you should receive LINEZOLID 600 mg/300 ml ASPEN after your dialysis treatment.

A course of treatment usually lasts 10 to 14 days but can last up to 28 days. The safety and effectiveness of this medicine have not been established for treatment periods longer than 28 days. Your doctor will decide how long you should be treated.

While you are receiving LINEZOLID 600 mg/300 ml ASPEN, your doctor should perform regular blood tests to monitor your blood count.

Your doctor should monitor your eyesight if you use or receive LINEZOLID 600 mg/300 ml ASPEN for more than 28 days.

Use in children and adolescents

LINEZOLID 600 mg/300 ml ASPEN is used to treat children and adolescents (under 18 years old).

Your doctor will tell you how long your treatment with LINEZOLID 600 mg/300 ml ASPEN will last. If you have the impression that the effect of LINEZOLID 600 mg/300 ml ASPEN is too strong or too weak, tell your doctor or pharmacist.

If you are given more LINEZOLID 600 mg/300 ml ASPEN than you should have been

Since a healthcare provider will administer LINEZOLID 600 mg/300 ml ASPEN, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

No cases of overdose have been reported. Supportive care is advised together with maintenance of glomerular filtration (the process during which the body makes urine).

If you are not given LINEZOLID 600 mg/300 ml ASPEN

As you will be given this medicine under close supervision, it is very unlikely that you will miss a dose. If you think that you have missed a dose of treatment, tell a doctor or nurse at once.

4. Possible side effects

LINEZOLID 600 mg/300 ml ASPEN can have side effects.

Not all side effects reported for LINEZOLID 600 mg/300 ml ASPEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LINEZOLID 600 mg/300 ml ASPEN, please consult your healthcare provider for advice.

If any of the following happens, stop taking/using LINEZOLID 600 mg/300 ml ASPEN 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, this may be signs of an allergic reaction,
- rash or itching,
- severe and bullous skin disorder, such as red sore skin and flaking (dermatitis), described as toxic epidermal necrolysis (TEN) or Stevens Johnson syndrome.

These are all very serious side effects. If you have them, you may have had a serious reaction to LINEZOLID 600 mg/300 ml ASPEN. 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:

- severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), which in rare circumstances may develop into complications that are life-threatening,
- rapid breathing,
- convulsions or fitting,

- you should let your doctor know if you experience agitation, confusion, delirium, rigidity, tremor, incoordination and seizure while also taking antidepressants known as SSRIs (see section 2). Serotonergic syndrome presents with symptoms such as confusion, agitation, rapid heart rate and high blood pressure,
- unexplained bleeding or bruising, which may be due to changes in the numbers of certain cells in the blood which may affect blood clotting or lead to anaemia,
- anaemia, a deficiency in the number and quality of red blood cells. Symptoms may include but are not limited to fatigue, weakness, the sensation of a pounding or racing heart (palpitations), shortness of breath, headaches, irritability, and chest pain,
- condition in which bone marrow activity is decreased, resulting in fewer red blood cells, white blood cells, and platelets (myelosuppression) which presents with symptoms such as fatigue, shortness of breath, dizziness,
- disease affecting the peripheral nerves that presented as sensations such as tingling or feeling numb, sharp or throbbing pain (peripheral neuropathy),
- blurred vision, pain when you move your eyes, trouble seeing to the side, loss of colour vision, blindness (optic neuropathy),
- exhaustion, extreme fatigue, muscle cramps or pain, body weakness, overall feeling of discomfort (lactic acidosis which is a form of metabolic acidosis that begins when a person overproduces or underutilises lactic acid).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- fungal infection of the mouth and throat (candidiasis) known as oral thrush,
- fungal infection (a vaginal yeast infection) known as vaginal thrush,

- headache,
- taste alteration; metallic taste in the mouth,
- a sensation of whirling and loss of balance (vertigo)
- diarrhoea, nausea (feeling sick), vomiting (being sick), stomach pain, cramps
,distension, loose stool
- abnormal blood tests (seen from laboratory results)
- abnormal liver test (seen from laboratory results)
- changes in some blood test results including those measuring your kidney or liver
function or blood sugar levels.

Less frequent side effects:

- changes in numbers of certain cells in the blood which may affect your ability to fight
infection (white blood cells) and can present with sore throat or mouth ulcers, causes
allergic responses (eosinophilia), affects clotting of the blood (thrombocytopenia),
- inflammation of the pancreas that presents with symptoms such as fever, rapid pulse,
abdominal pain that radiates to your back.
- inflammation of the vagina or genital area in women,
- reduce sense of touch or sensation, or a partial loss of sensitivity to sensory stimuli
(hypoaesthesia),
- increased or decreased blood pressure,
- swollen; sore or discoloured tongue,
- tooth discolouration,
- a need to urinate more often (polyuria),
- constipation, dry mouth, inflammation of the lining of the stomach (gastritis),
inflammation of the inside of the mouth (stomatitis),

- feeling thirsty,
- dizziness,
- inability to sleep (insomnia),
- heavy sweating (diaphoresis,)
- changes in proteins, salts or enzymes in the blood which measure kidney or liver function,
- low blood sugar without diabetes (decreased non-fasting glucose),
- increase in sodium and calcium levels (determined by laboratory tests),
- increased or decreased chloride (determined by laboratory tests),
- dyspepsia (indigestion),
- increase in creatinine (waste product in the body,)
- muscle tissue damage (increased serum creatine phosphokinase),
- high blood sugar level (hyperglycaemia),
- ringing in the ears (tinnitus),
- increased or decreased blood pressure,
- chills, tiredness; fever;(increase in body temperature),
- pain at the site of administration, localised pain (exists in one part of your body, and hasn't spread to other places in the body)

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: <https://www.sahpra.org.za/health-products-vigilance/>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of LINEZOLID 600 mg/300 ml ASPEN.

5. How to store LINEZOLID 600 mg/300 ml ASPEN

Store all medicines out of reach of children.

Store at or below 30 °C. Keep the polyethylene container in the outer carton in order to protect from light.

Single use only.

Do not store in a bathroom.

- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LINEZOLID 600 mg/300 ml ASPEN contains

The active substance is 2 mg linezolid per ml.

The other ingredients are citric acid anhydrous, glucose monohydrate, hydrochloric acid (for pH adjustment) sodium citrate, sodium hydroxide (for pH adjustment), water for injections.

What LINEZOLID 600 mg/300 ml ASPEN looks like and contents of the pack

300 ml of LINEZOLID 600 mg/300 ml ASPEN is filled into a polyethylene bag and packed in a cardboard carton. The product is a clear, colourless to yellow solution.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead, 2191

Hotline: 0800 118 088

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