PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LINEZOLID 600 mg/300 ml FRESENIUS solution for infusion

Linezolid

Contains sugar: Glucose monohydrate 15,072 g

Read all of this leaflet carefully before you are given LINEZOLID FRESENIUS

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

1. What LINEZOLID FRESENIUS is and what it is used for

The active ingredient, linezolid, is an antibiotic of the so-called oxazolidinones group. It acts by stopping the growth of certain bacteria (germs) that cause infections.

LINEZOLID FRESENIUS is used by your doctor to treat pneumonia and manage some infections in the skin or under the skin. Your doctor will decide if LINEZOLID FRESENIUS is suitable to be used for the type of infection you have.

2. What you need to know before you are given LINEZOLID FRESENIUS

LINEZOLID FRESENIUS should not be administered to you:

- if you are hypersensitive (allergic) to linezolid or any of the other ingredients of LINEZOLID FRESENIUS (listed in section 6).
- if you are treated with monoamine oxidase inhibitors (examples of MAOIs are phenelzine, selegiline, moclobemide) or within 2 weeks of taking such a medicine. These medicines may be used to treat depression or Parkinson's disease.
- if you breastfeed your baby.

Warnings and precautions

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

- if you have high blood pressure and what medicines you are taking for this (see section 2, "Other medicines and LINEZOLID FRESENIUS");
- if you have been diagnosed with an overactive thyroid gland (symptoms may be increased appetite, weight loss or sweating);
- 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 suffer from manic depression, schizoaffective disorder (a mental condition that causes both a loss of contact with reality and mood problems), mental confusion or other mental problems;

- if you have recurrent nausea or vomiting, abdominal pain or over breathing (a condition known as lactic acidosis, it is when lactic acid builds up in the bloodstream faster than it can be removed and can be life-threatening);
- if you have been diagnosed with anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness);
- if you bruise and bleed easily;
- if you get infections easily;
- if you have a history of seizures (“fits”) or if you experienced agitation, confusion, coma, stiff muscles, trembling, poor coordination and fits while also taking antidepressants known as SSRIs;
- if you have liver or kidney problems (especially if you have dialysis);
- if you have diarrhoea (see section 4);
- if you take or are given any medicines for cold and flu, asthma, depression, migraine, sudden severe allergic reactions, blood pressure, severe pain, anxiety, other infections. See section 2 “Other medicines and LINEZOLID FRESENIUS” for more information;
- if you have porphyria (a rare inherited blood disease).

You should also know that:

- LINEZOLID FRESENIUS may cause serious diarrhoea and infection in the bowels (see section 4). You may develop diarrhoea while taking, or after taking antibiotics, including LINEZOLID FRESENIUS. If this becomes severe or persistent or you notice that your stool contains blood or mucus, treatment with LINEZOLID FRESENIUS should be stopped immediately and your doctor consulted. In this situation, you should not take medicines that stop or slow bowel movement.

- LINEZOLID FRESENIUS may cause vision problems (see section 4). 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.
- Lactic acidosis: Tell your doctor if you have muscle aches, burning, rapid breathing, nausea, stomach pain. See section 4 for more information on side effects.
- If you are an elderly person, you are at a greater risk of developing blood disorders such as anaemia, lower white cell counts, and lower platelet counts. As you will be in hospital, regular blood tests may help reveal blood disorders.
- Unexplained muscle pain, tenderness, or weakness, and/or dark urine. These can be signs of a serious condition called rhabdomyolysis (muscle breakdown), which can lead to kidney damage.

Other medicines and LINEZOLID FRESENIUS

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

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important with the medicines listed below.

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

- Some medicines used to treat asthma such as salbutamol, terbutaline, fenoterol.
- Medicines used to treat migraine such as sumatriptan and zolmitriptan.
- 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 (selective serotonin reuptake inhibitors), for example amitriptyline, citalopram, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine and sertraline.
- Medicines used to treat anxiety disorders, such as buspirone.
- Medicines used to treat moderate to severe pain, such as pethidine.
- Medicines that stop blood clotting, such as warfarin.
- An antibiotic for TB called rifampicin.

LINEZOLID FRESENIUS with food, drink and alcohol

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 this medicine 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 health care provider for advice before you receive LINEZOLID FRESENIUS.

The effect of LINEZOLID FRESENIUS in pregnant women is unknown; it should therefore not be used during pregnancy.

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

Driving and using machines

LINEZOLID FRESENIUS may make you feel dizzy or experience problems with your vision (see section 4). Do not drive or use tools or machines if this happens, as LINEZOLID FRESENIUS could interfere with your ability to drive safely.

It is not always possible to predict to what extent LINEZOLID FRESENIUS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LINEZOLID FRESENIUS affects them.

LINEZOLID FRESENIUS contains sugar (glucose) and sodium

Glucose

LINEZOLID FRESENIUS contains 15,072 g glucose monohydrate per 300 mL solution. Please tell your doctor or nurse if you are diabetic or if you have glucose intolerance.

Sodium

LINEZOLID FRESENIUS also contains 131 mg sodium (as sodium citrate) per 300 mL solution. Please tell your doctor or nurse if you are on a low sodium diet.

3. How LINEZOLID FRESENIUS will be administered to you

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

LINEZOLID FRESENIUS is normally administered in hospital and will be infused (dripped) into a large vein.

Your doctor will tell you how long your treatment with LINEZOLID FRESENIUS 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 below under “If you stop receiving LINEZOLID FRESENIUS”).
If you have the impression that the effect of LINEZOLID FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

If you receive more LINEZOLID FRESENIUS than you should

Since a health care provider will administer LINEZOLID FRESENIUS, 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 LINEZOLID FRESENIUS.

If you forget to receive LINEZOLID FRESENIUS

You need not remember when to get your next dose; you will be cared for in hospital/clinic by a professional health care provider, who will ensure that you receive the correct amount of LINEZOLID FRESENIUS at the right time.
If you think you have missed a dose, please ask your doctor or health care provider.
Do not receive a double dose to make up for forgotten individual doses.

If you stop receiving LINEZOLID FRESENIUS

To clear up your infection completely, LINEZOLID FRESENIUS 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 early may have the effect that the germs causing the infection become resistant to LINEZOLID FRESENIUS.

4. Possible side effects

LINEZOLID FRESENIUS can have side effects.

Not all side effects reported for LINEZOLID FRESENIUS are included in this leaflet. Should your general health worsen of if you experience any untoward effects while receiving LINEZOLID FRESENIUS, please consult your health care provider for advice.

Your medical condition will also be carefully monitored in a hospital or clinic.

Your doctor/nurse will notice if you get any of the following very serious side effects (frequency unknown):

- Severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), or bacterial infection of the bowels, which in rare circumstances may develop into complications that are life-threatening.
- Serious allergic reactions, including a shock reaction. You may have swelling of the tongue and/or throat, difficulty in swallowing, difficulties in breathing, facial swelling, severe dizziness with very fast heartbeat and heavy sweating.
- Skin reactions such as hives (nettle rash), red sore skin and flaking (dermatitis), rash, itching, or swelling, particularly around the face and neck. This may be a sign of a severe allergic reaction, and it may be necessary that treatment with LINEZOLID FRESENIUS be stopped.
- Lactic acidosis (signs may be 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 can be life-threatening.
- Fits or seizures (see “Tell your doctor or health care provider before being given LINEZOLID FRESENIUS injection”).

- Serotonin syndrome (which is an excessive accumulation of serotonin in your body and causes symptoms like fast heart rate, confusion, abnormal sweating, hallucinations, involuntary movements, chills and shivering). Serotonin syndrome is a very serious condition which may occur when two medicines that affect the body's level of serotonin are administered together at the same time. See section 2 “Other medicines and LINEZOLID FRESENIUS”.
- Problems with your vision such as 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).
- Rhabdomyolysis (rare): Signs and symptoms include unexplained muscle pain, tenderness, or weakness, and/or dark urine. These can be signs of a serious condition called rhabdomyolysis (muscle breakdown), which can lead to kidney damage.

Your doctor will stop giving you LINEZOLID FRESENIUS and you will be given urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects occurring frequently:

- Fungal infections, especially vaginal or oral “thrush”.
- 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.
- Headache.
- 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.

Side effects occurring less frequently

- 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.
- Difficulty in sleeping.
- Dizziness, sensations such as tingling or numbness of fingers and toes.
- Convulsions (“fits”).
- Blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.
- “Ringing” in the ears (tinnitus).
- Changes in heart rate (e.g., increased rate).
- Increased blood pressure (your doctor will test your blood pressure) inflammation of the veins.
- Indigestion, stomach pain, constipation, distended belly, thirst, loose stools.
- Dry or sore mouth, swollen, sore, or discoloured tongue.
- Hair loss, sweating, itching.
- Superficial tooth discolouration.
- Kidney failure, excessive or abnormally large production or passage of urine.

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

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed either directly or via the national pharmacovigilance electronic reporting systems.

5. How to store LINEZOLID FRESENIUS

Store at room temperature, at or below 25 °C. Do not freeze. Protect from light – the infusion bags must be kept in their overpouch, until ready to use. The infusion bags and KabiPac bottles are only intended for single use. Discard any unused solution.
KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.
Your health care provider will check that the LINEZOLID FRESENIUS 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 LINEZOLID FRESENIUS contains

The active substance is linezolid.
Each 300 mL infusion bag or bottle of LINEZOLID FRESENIUS contains 600 mg linezolid: providing 2 mg linezolid per mL.

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

Contains sugar: Glucose monohydrate 15,072 g.

What LINEZOLID FRESENIUS looks like and contents of the pack

Freeflex bags:

LINEZOLID FRESENIUS is presented as a clear, practically free from particles, colourless to yellow solution in single infusion bags containing 300 mL (600 mg linezolid) of solution.

KabiPac bottles:

LINEZOLID FRESENIUS is presented as a clear, practically free from particles, colourless to yellow or slightly brownish solution in single infusion bottle containing 300 mL (600 mg linezolid) of solution.

FreeFlex bags

Single use freeflex infusion bags packaged in an aluminium foil overpouch, available in a pack size of 300 mL (600 mg linezolid).

The freeflex® container closure system for LINEZOLID FRESENIUS solution for infusion consists of three components: film, ports (tubes and closure system consisting of stoppers and caps) and hot stamp foil ink. A printed overwrap provides additional product protection from loss of water (via permeation) as well as protection from light. Packed as 10 x 300 mL.

KabiPac bottles

300 mL solution is filled into a 500 mL KabiPac bottle. The KabiPac packaging system consists of a polyethylene bottle and a cap with an administration point and an addition point, which are two separate, easily distinguishable ports for infusion and injection. The cap is made of polyethylene or a mixture of polyethylene and polypropylene.
Inside the cap, two polyisoprene stoppers serve for the insertion and support of the needle or the spike. The KabiPac packaging system is a unit dose container with a hanger at the bottom of the bottle.
The KabiPac bottles are packed individually into cartons. Ten such single-packed bottles are then packed into an outer carton in pack sizes of 10 x 300 mL.

Holder of Certificate of Registration

Fresenius Kabi South Africa (Pty) Ltd
Stand 7 Growthpoint Business Park
162 Tonetti Street, Halfway House extension 7
Midrand, Gauteng
1685
SOUTH AFRICA
Telephone number: +27 (0) 11 545 0000

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Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: **S4**

LINEZOLID 600 mg/300 ml FRESENIUS oplossing vir infusie

Linesolied

Bevat suiker: Glukosemonohidraat 15,072 g

Lees die hele inligtingsblad aandagtig deur voordat LINEZOLID FRESENIUS aan jou gegee word

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, raadpleeg asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.

Wat is in hierdie inligtingsblad

1. Wat is LINEZOLID FRESENIUS en waarvoor word dit gebruik
2. Wat jy moet weet voordat LINEZOLID FRESENIUS aan jou gegee word
3. Hoe LINEZOLID FRESENIUS aan jou gegee word
4. Moontlike newe-effekte
5. Hoe om LINEZOLID FRESENIUS te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat is LINEZOLID FRESENIUS en waarvoor word dit gebruik

Die aktiewe bestanddeel, linesolied, is 'n antibiotikum van die sogenaamde oksasolidinoongroep. Dit werk deur die groei van sekere bakterieë (kieme) wat infeksies veroorsaak, te verhoed.

LINEZOLID FRESENIUS word deur jou dokter gebruik om pneumonie te behandel en om sekere infeksies van die vel of onder die vel te behandel. Jou dokter sal besluit of LINEZOLID FRESENIUS geskik is vir die tipe infeksie wat jy het.

2. Wat jy moet weet voordat LINEZOLID FRESENIUS aan jou gegee word

LINEZOLID FRESENIUS moet nie aan jou toegedien word nie:

- indien jy hipersensitief (allergies) is vir linesolied of enige van die ander bestanddele van LINEZOLID FRESENIUS (gelys in afdeling 6).
- indien jy behandel word met monoamienoksidase-inhibitore (voorbeelde van MAOI's is fenelsien, selegilien, moklobemied), of binne 2 weke nadat jy so 'n medisyne geneem het. Hierdie medisyne kan gebruik word om depressie of Parkinson se siekte te behandel.
- indien jy jou baba borsvoed.

Waarskuwings en voorsorgmaatreëls

Lig jou dokter of gesondheidsorgverskaffer in voordat LINEZOLID FRESENIUS inspuiting aan jou gegee word:

- indien jy hoë bloeddruk het en watter medisyne jy daarvoor neem (sien afdeling 2, "Ander medisyne en LINEZOLID FRESENIUS");
- indien jy met 'n ooraktiewe skildklier (simptome kan verhoogde eetlus, gewigsverlies of sweet insluit) gediagnoseer is;
- indien jy 'n gewas van die byniere (feochromositoom) of karsinoïed-sindroom het (veroorsaak deur gewasse van die hormoonstelsel met simptome van diarree, velgloede, hyging);

- indien jy aan maniese depressie, skiso-affektiewe steuring ('n geestessiekte wat beide 'n verlies aan kontak met die werklikheid en gemoedsprobleme veroorsaak), verstandelike verwarring of ander geestesgesondheidsprobleme ly;
- indien jy herhalende naarheid of braking, buikpyn of jaagasemhaling ervaar ('n toestand bekend as melksuurasidose, waar melksuur vinniger in die bloedstroom opbou as wat dit afgebreek kan word en wat lewensgevaarlik kan wees);
- indien jy gediagnoseer is met anemie (vermindering in rooibloedselle, wat die vel bleek laat lyk en swakheid of kortasemheid kan veroorsaak);
- indien jy maklik kneus en bloei;
- indien jy maklik infeksies kry;
- indien jy 'n geskiedenis van aanvalle (“stuipe”) het of as jy rusteloosheid, verwarring, koma, spierstyfheid, bewing, swak koördinasie en stuiptrekkings ervaar het terwyl jy antidepressante (sogenaamde SSHIs) gebruik het;
- indien jy lewer- of nierprobleme het (veral as jy dialise ondergaan);
- indien jy diarree het (sien afdeling 4);
- indien jy enige medisyne vir verkoue en griep, asma, depressie, migraine, skielike erge allergiese reaksies, bloeddruk, erge pyn, angs, ander infeksies, neem of ontvang. Sien afdeling 2 "Ander medisyne en LINEZOLID FRESENIUS" vir meer inligting;
- indien jy porfirie het ('n seldsame oorgeërfde bloedsiekte).

Jy moet ook weet dat:

- LINEZOLID FRESENIUS kan ernstige diarree en derminfeksies veroorsaak (sien afdeling 4). Jy kan diarree ontwikkel terwyl of nadat jy antibiotika, insluitend LINEZOLID FRESENIUS, geneem het. Indien hierdie simptome ernstig word of voortduur, of jy sien dat jou stoelgang bloed of slym bevat, moet behandeling met

LINEZOLID FRESENIUS onmiddellik gestaak word en jou dokter geraadpleeg word. In hierdie situasie moet jy nie medisyne neem wat stoelgang stop of vertraag nie.

- LINEZOLID FRESENIUS kan sigprobleme veroorsaak (sien afdeling 4). Lig jou dokter dadelik in as jy sigprobleme ervaar, soos versteurde visie, veranderinge in kleurvisie, probleme om detail te sien of 'n verkleining van jou gesigsveld.
- Laktasidose: Lig jou dokter in as jy spierpyne, brandgevoel, vinnige asemhaling, naarheid en maagpyn het. Sien afdeling 4 vir meer inligting oor newe-effekte.
- Indien jy bejaard is, loop jy 'n groter risiko om bloedsiektes soos anemie, laer witbloedseltellings en 'n laer bloedplaatjietellings te ontwikkel. Aangesien jy in die hospitaal is, kan gereelde bloedtoetse help om bloedafwykings op te spoor.
- Onverklaarbare spierpyn, teerheid of swakheid, en/of donker urien. Dit kan tekens wees van 'n ernstige siektetoestand genaamd rabdomiolise (spierafbraak), wat tot nierskade kan lei.

Ander medisyne en LINEZOLID FRESENIUS

Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).

Lig asseblief jou dokter of verpleegster in as jy tans of onlangs enige ander medisyne, ook medisyne wat jy sonder 'n voorskrif verkry het, neem of geneem het. Dit is veral belangrik met die medisyne wat hieronder gelys word.

- Jy moet **nie** LINEZOLID FRESENIUS ontvang as jy tans MAOI's (bv. fenelsien, isokarboksasied, selegilien, moklobemied) neem of dit binne die afgelope 14 dae geneem het nie. Hierdie medisyne kan gebruik word vir die behandeling van depressie of Parkinson se siekte. Sien "LINEZOLID FRESENIUS moet nie aan jou gegee word nie".

- Jou dokter kan 'n ander medisyne oorweeg as jy tans die volgende medisyne neem/gebruik, of onlangs gebruik het:
  - Ontstuwingsmiddels of verkoue- of griepmedisynes wat pseudoëfedrien of fenielpropanolamien bevat.
  - Sommige medisyne gebruik vir die behandeling van asma, soos salbutamol, terbutalien, fenoterol.
  - Medisyne gebruik vir die behandeling van migraine, soos sumatriptaan en solmitriptaan.
  - Medisyne gebruik vir die behandeling van skielike, erge allergiese reaksies, soos epinefrien (adrenalien).
  - Medisyne wat jou bloeddruk verhoog, soos norepinefrien (noradrenalien), dopamien en dobutamien.
  - Sekere antidepressante bekend as trisikliese antidepressante of SSHIs (selektiewe serotonienheropname-inhibitore), byvoorbeeld amitriptilien, sitalopraam, klomipramien, dosulepien, doksepien, fluoksetien, fluvoksamien, imipramien, lofepramien, paroksetien en sertralien.
  - Medisyne gebruik vir die behandeling van angssteurings, soos buspiroon.
  - Medisyne gebruik vir die behandeling van matige tot erge pyn, soos petidien.
  - Medisyne wat bloedstolling voorkom, soos warfarien.
  - 'n Antibiotikum vir TB (tering), genaamd rifampisien.

LINEZOLID FRESENIUS met voedsel, drank en alkohol

Vermy die inname van groot hoeveelhede verouderde kaas, gisekstrakte of sojaboonekstrakte (bv. sojasous) en alkohol, veral tapbiere en wyn. Dit is omrede hierdie medisyne kan reageer met 'n stof genaamd tiramien, wat van nature in sommige kosse

voorkom, wat dan 'n toename in 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 LINEZOLID FRESENIUS ontvang.

Die effek van LINEZOLID FRESENIUS in swanger vroue is onbekend, dus moet dit nie tydens swangerskap gebruik word nie.

Jy moet nie jou baba borsvoed terwyl jy LINEZOLID FRESENIUS ontvang nie, want dit kom in borsmelk voor en kan dalk jou baba aantas.

Bestuur en die gebruik van masjinerie

LINEZOLID FRESENIUS kan jou duiselig laat voel of probleme met jou visie laat ervaar (sien afdeling 4). Moet nie bestuur of gereedskap of masjinerie gebruik nie omdat LINEZOLID FRESENIUS jou vermoë om veilig te bestuur kan beïnvloed.

Dit is nie altyd moontlik om te voorspel tot hoe 'n mate LINEZOLID FRESENIUS die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet seker maak dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle bewus is tot hoe 'n mate LINEZOLID FRESENIUS hulle aantas nie.

LINEZOLID FRESENIUS bevat suiker (glukose) en natrium

Glukose

LINEZOLID FRESENIUS bevat 15,072 g glukosemonohidraat per 300 mL oplossing. Lig asseblief jou dokter of verpleegster in as jy diabeties is of as jy 'n onverdraagsaamheid vir glukose het.

Natrium

LINEZOLID FRESENIUS bevat ook 131 mg natrium (as natriumsitraat) per 300 mL oplossing. Lig asseblief jou dokter of verpleegster in as jy op 'n lae-natrium dieet is.

3. Hoe LINEZOLID FRESENIUS aan jou gegee word

Daar sal nie van jou verwag word om LINEZOLID FRESENIUS aan jouself toe te dien nie. Dit sal deur 'n gekwalifiseerde persoon aan jou gegee word.

LINEZOLID FRESENIUS word gewoonlik in die hospitaal gegee en word deur infusie (drup) in 'n groot aar gegee.

Jou dokter sal jou inlig hoe lank jou behandeling met LINEZOLID FRESENIUS sal duur. Moenie die behandeling vroegtydig staak nie, aangesien 'n volledige kursus antibiotikum nodig is om die kieme wat jou siek maak dood te maak (sien hieronder “Indien jy ophou om LINEZOLID FRESENIUS te ontvang”).

Indien jy die indruk kry dat die effek van LINEZOLID FRESENIUS te sterk of te swak is, lig jou dokter of apteker in.

Indien jy meer LINEZOLID FRESENIUS ontvang het as wat jy moes

Aangesien 'n gesondheidsorgverskaffer LINEZOLID FRESENIUS sal toedien, sal hy/sy die dosis beheer. In geval van oordosering sal jou dokter egter die oordosering behandel.

Lig jou dokter of gesondheidsorgverskaffer dadelik in as jy dink dat jy te veel LINEZOLID FRESENIUS ontvang het.

Indien 'n dosis LINEZOLID FRESENIUS oorgeslaan is

Jy hoef nie te onthou wanneer jy jou volgende dosis moet kry nie; jy sal in 'n hospitaal/kliniek deur 'n gesondheidsorgverskaffer versorg word, wat seker sal maak dat jy die regte hoeveelheid LINEZOLID FRESENIUS op die regte tyd kry.
Indien jy dink dat 'n dosis oorgeslaan was, vra asseblief jou dokter of gesondheidsorgverskaffer.
Moenie 'n dubbele dosis ontvang om te vergoed vir individuele dosisse wat vergeet is nie.

Indien jy ophou om LINEZOLID FRESENIUS te ontvang

Om jou infeksie heeltemal op te klaar moet die volle behandelingskursus van LINEZOLID FRESENIUS soos deur jou dokter voorgeskryf, gebruik word.
Jou simptome kan verbeter voordat die infeksie volledig behandel is. Voortydige staking kan veroorsaak dat die kieme wat die infeksie veroorsaak het weerstandig word tot LINEZOLID FRESENIUS.

4. Moontlike newe-effekte

LINEZOLID FRESENIUS kan newe-effekte hê.

Nie alle newe-effekte wat vir LINEZOLID FRESENIUS aangemeld is, is by hierdie inligtingsblad ingesluit nie.

Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl jy LINEZOLID FRESENIUS ontvang, raadpleeg asseblief jou gesondheidsorgverskaffer.

Jou mediese toestand sal deeglik in 'n hospitaal of kliniek gemonitor word.

Jou dokter/verpleegster sal sien as jy enige van die volgende baie ernstige newe-effekte ervaar (frekwensie onbekend):

- Erge diarree met bloed en/of slym (antibiotikum-geassosieerde kolitis insluitend pseudomembraneuse kolitis) of bakteriële infeksie van die dermkanaal, wat in seldsame gevalle tot lewensgevaarlike komplikasies kan lei.
- Ernstige allergiese reaksies, wat 'n skok-reaksie kan insluit. Jy kan die volgende ervaar: 'n geswelde tong en/of keel, sukkel om te sluk of asem te haal, swelling van die gesig, erge duiseligheid met 'n baie vinnige hartklop en baie sweet.
- Velreaksies soos netelroos (galbulte), rooi seer vel en afskilfering (dermatitis), uitslag, jeuk of swelling, veral om die gesig en nek. Dit kan 'n teken wees van 'n ernstige allergiese reaksie en dit kan nodig word om behandeling met LINEZOLID FRESENIUS te staak.
- Laktasidose (herhalende naarheid of braking, buikpyn of jaagasemhaling kan tekens daarvan wees). Laktasidose kom voor as melksuur vinniger in die bloedstroom ophoop as wat dit verwyder kan word en kan lewensgevaarlik wees.
- Toevalle of stuiptrekkings (sien “Lig jou dokter of gesondheidsorgverskaffer in voordat LINEZOLID FRESENIUS inspuiting aan jou gegee word”).
- Serotoniensindroom (dit is 'n oormatige ophoping van serotonien in jou liggaam, wat simptome soos vinnige hartklop, verwarring, abnormale sweet, hallusinasies, onwillekeurige bewegings, kouekoors en bewerasie veroorsaak). Serotoniensindroom is 'n baie ernstige toestand wat kan voorkom wanneer twee middels wat die liggaam se serotonienvlakke beïnvloed, gelyktydig toegedien word. Sien afdeling 2 “Ander medisyne en LINEZOLID FRESENIUS”.
- Probleme met jou visie, soos dowwe visie, veranderinge in kleurwaarneming, sukkel om detail te sien of jou gesigsveld raak beperk.

- Verbygaande iskemiese aanvalle (“mini-beroerte” met tekens soos 'n tydelike versteuring van bloedvloei na die brein wat korttermynsimptome soos verlies van sig, swakheid in die bene en arms, sleepspraak en verlies van bewussyn veroorsaak).
- Rabdomiolise (skaars): Tekens en simptome sluit in: onverklaarbare spierpyn, teerheid of swakheid, en/of donker urien. Dit kan tekens wees van 'n ernstige siektetoestand genaamd rabdomiolise (spierafbraak), wat tot nierskade kan lei.

Jou dokter sal ophou om LINEZOLID FRESENIUS aan jou te gee en jy sal dringende mediese aandag ontvang.

Lig jou dokter in as jy enige van die volgende waarneem:

Newe-effekte wat gereeld voorkom:

- Swaminfeksies, veral vaginale of mond “sproei”
- Onverklaarbare bloeding of kneusing, moontlik weens verandering in die hoeveelheid van sekere selle in die bloed, wat bloedstolling kan beïnvloed of tot anemie kan lei.
- Hoofpyn.
- Metaalsmaak in mond.
- Naarheid (mislike gevoel), braking (opbring), buikpyne, diarree (los stoelgang).
- Veranderinge in sommige bloedtoetsresultate insluitend dié wat jou nier- of lewerfunksie of bloedsuikervlakke bepaal.

Newe-effekte wat minder gereeld voorkom

- Ontsteking van die vagina of genitale area by vroue.
- Veranderinge in die hoeveelheid van sekere selle in die bloed wat jou vermoë om infeksies te bestry kan beïnvloed.
- Sukkel om te slaap.
- Duiseligheid, sensasies soos tinteling of gevoelloosheid van die vingers en tone.

- Konvulsies ("stuipe").
- Dowwe visie, veranderinge in kleurvisie, sukkel om detail te sien, of 'n beperkte gesigsveld.
- "Gesuis" in die ore (tinnitus).
- Verandering in harttempo (bv. verhoogde tempo).
- Verhoogde bloeddruk (jou dokter sal jou bloeddruk toets), inflammasie van die are.
- Slegte spysvertering, maagpyn, hardlywigheid, opgehewe buik, dors, los stoelgange.
- Droë of seer mond, geswelde, seer of verkleurde tong.
- Haarverlies, sweet, jeuk.
- Oppervlakkige tandverkleuring.
- Nierversaking, uitermatige of abnormaal verhoogde vorming of passering van urien.

Indien jy enige newe-effekte ondervind wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte

Indien jy newe-effekte ervaar, bespreek dit met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en die eReporting-platform (who-umc.org) op die SAHPRA webwerf. Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van LINEZOLID FRESENIUS te verskaf.

Pasiënte word versoek om enige vermoedelike ongunstige newe-effekte van geneesmiddels aan hulle gesondheidsorgverskaffer of die Houer van die Registrasiesertifikaat by die volgende e-posadres aan te meld: safety.fksa@fresenius-kabi.com en aan die betrokke medisyne se regulatoriese owerheid in die land waar die

produk bemark word, direk of via die nasionale elektroniese geneesmiddelveiligheidsrapporteringstelsels.

5. Hoe om LINEZOLID FRESENIUS te bewaar

Bewaar by kamertemperatuur, by of onder 25 °C. Moenie vries nie. Beskerm teen lig - die infusiesakke moet in die buitesak gehou word totdat dit gereed is om te gebruik. Die infusiesakke en KabiPac bottels is slegs bedoel vir eenmalige gebruik. Gooi alle ongebruikte oplossing weg.

HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

Jou gesondheidsorgverskaffer sal voordat die inspuiting aan jou gegee word seker maak of LINEZOLID FRESENIUS nie reeds die vervaldatum wat op die etiket en karton aangebring is, bereik het nie.

Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie. Neem alle ongebruikte medisyne terug na jou apteker.

6. Inhoud van die pakkie en ander inligting

Wat LINEZOLID FRESENIUS bevat

Die aktiewe bestanddeel is linesolied.

Elke 300 mL infusiesak van LINEZOLID FRESENIUS bevat 600 mg linesolied, wat 2 mg linesolied per mL verskaf.

Die ander bestanddele is water vir inspuiting, glukosemonohidraat, natriumsitraat, anhidriese sitroensuur, soutsuur (vir pH-instelling) en natriumhidroksied (vir pH-instelling).

Bevat suiker: Glukosemonohidraat 15,072 g.

Hoe LINEZOLID FRESENIUS lyk en inhoud van die pakkie

FreeFlex sakke:

LINEZOLID FRESENIUS word aangebied as 'n helder, feitlik vry van deeltjies, kleurlose tot geel oplossing in enkele infusiesakke wat 300 mL (600 mg linesolied) oplossing bevat.

KabiPac bottels:

LINEZOLID FRESENIUS word aangebied as 'n helder, feitlik vry van deeltjies, kleurlose tot geel of effens bruinerige oplossing in 'n enkele infusiebottel wat 300 mL (600 mg linesolied) oplossing bevat.

FreeFlex sakke

Eenmalige gebruik freeflex infusiesakke verpak in 'n aluminiumfoelie buitesak, beskikbaar in 'n pakgrootte van 300 mL (600 mg linesolied).

Die freeflex® houertoemaakstelsel vir LINEZOLID FRESENIUS infusie-oplossing bestaan uit drie komponente: foelie, poorte (buise en sluitingstelsel bestaande uit proppe en doppies) en warmdrukfoelie-ink. ’n Gedrukte omslag beskerm ook die produk teen waterverlies (weens vogdeurlaatbaarheid) en teen lig. Verpak in 10 x 300 mL.

KabiPac bottels

300 mL oplossing word in 'n 500 mL KabiPac bottel gevul. Die KabiPac-verpakkingstelsel bestaan uit 'n poliëtileenbottel en 'n dop met 'n toedieningspunt en 'n toevoegingspunt. Dit is twee afsonderlike, maklik onderskeibare poorte vir infusie en inspuiting. Die dop word uit poliëtileen of 'n mengsel van poliëtileen en polipropileen vervaardig.

Binne-in die doppie dien twee poli-isopreenproppe vir die invoeging en ondersteuning van die naald of die spyker. Die KabiPac-verpakkingstelsel is 'n eenheidsdosishouer met 'n hanger aan die onderkant van die bottel.

Die KabiPac bottels word individueel in kartonne verpak. Tien sulke enkelverpakte bottels word dan in 'n buitekarton in pakgroottes van 10 x 300 mL verpak.

Houer van die Registrasiesertifikaat

Fresenius Kabi South Africa (Pty) Ltd

Stand 7, Growthpoint Business Park

Tonettistraat 162, Halfway House Extension 7

Midrand, Gauteng 1685

SUID-AFRIKA

Telefoonnommer: +27 (0) 11 545 0000

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Toegang tot die ooreenstemmende Professionele Inligting

Die professionele inligting sal gedruk word en saam met die produk verpak word.