PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ZYVOXID 600 mg/300 mL Solution for infusion

Linezolid

Contains sugar

ZYVOXID solution for infusion contains 50,24 mg per mL of sugar (dextrose monohydrate).

Read all of this leaflet carefully before you are given ZYVOXID

- 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.

ZYVOXID has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What ZYVOXID is and what it is used for

The active ingredient (linezolid) is an antibiotic that stops the growth of certain types of bacteria (germs) that cause infections. ZYVOXID is used to treat pneumonia and some infections in the skin or under the skin.

Your doctor will decide if ZYVOXID is suitable to treat your infection.

2. What you need to know before you use ZYVOXID

ZYVOXID should not be administered to you

- if you are hypersensitive (allergic) to linezolid or any of the other ingredients of ZYVOXID (listed in section 6).
- if you are taking or have taken within the last 2 weeks any medicines known as monoamine oxidase inhibitors (for example phenelzine, isocarboxazid). These medicines may be used to treat depression or Parkinson's disease.
- if you are pregnant or breastfeeding.

ZYVOXID may not be suitable for you if you answer YES to any of the following questions. 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 have high blood pressure
- if you been diagnosed with an overactive thyroid gland
- if you have a tumour of the adrenal glands (phaeochromocytoma)
- if you are taking a decongestant, cold or flu remedies containing pseudoephedrine or phenylpropanolamine
- if you are taking medicines used to raise blood pressure (e.g. epinephrine, norepinephrine)
- if you are taking medicines used to treat certain psychiatric or mental conditions and Parkinson's disease (e.g. dopamine, dobutamine)

Your doctor will monitor you for signs and symptoms of serotonin syndrome. ZYVOXID will not be given to you

- if you are taking antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors) or you have carcinoid syndrome (caused by tumours of the hormone system with symptoms of diarrhoea, flushing of the skin and wheezing)
- if you are taking medicines used to treat migraine (triptans)
- if you are taking medicines used to treat moderate to severe pain, such as meperidine
- if you are taking medicines used to treat anxiety disorders such as buspirone

Warnings and precautions

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

- if you bruise and bleed easily
- if you are anaemic (lack of iron in the blood / decreased numbers of red blood cells)
- if you suffer from liver or kidney problems. A low platelet count can happen more often in people who have serious kidney problems (with or without dialysis) or in people who have mild to severe liver problems
- if you take medicines that may decrease your haemoglobin levels
- if you use ZYVOXID for more than 2 weeks
- if you have diarrhoea as ZYVOXID leads to an overgrowth of a bacteria called *C. difficile* in the colon
- if you have 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.
- if you are feeling sick and unwell with muscle weakness, headache, confusion and memory impairment which may indicate hyponatraemia (low blood sodium levels).
- if you have a history of hyponatraemia (low blood sodium levels), are elderly or if you take medicines that lower blood sodium levels e.g. certain diuretics (also called “water tablets”) such as hydrochlorothiazide. It is recommended that your serum sodium levels are regularly monitored by your health care provider.
- 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
- if you have recurrent nausea or vomiting, abdominal pain or over-breathing (lactic acidosis)
- if you have convulsions or a history of seizures
- if you suffer from a life-threatening infection like suffering from infections that need a catheter in the large vein and are placed in the intensive care units
- if you have liver problems or kidney problems particularly if you have dialysis

Your doctor will monitor your vision if you are receiving ZYVOXID for more than 3 months or even if you report problems with your vision regardless the length of therapy.

You may develop diarrhoea while receiving or after receiving ZYVOXID. If this becomes severe or persistent or you notice that your stool contains blood or mucous, you should stop receiving ZYVOXID immediately and consult your doctor. In this situation, you should not take medicines that stop or slow bowel movement.

You should let your doctor know if you experience agitation (feeling of being worried or upset), confusion (feeling that you cannot decide what to do), delirium (confused state/extreme excitement or happiness), rigidity (stiffness), tremor (shake), incoordination (unable to control muscle movements) and seizure while also taking antidepressants known as SSRI's.

Other medicines and ZYVOXID

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

Tell your doctor if you are taking the following medicines as there is a risk that ZYVOXID may interact with certain other medicines to cause side effects such as changes in blood pressure, temperature or heart rate:

- monoamine oxidase inhibitors (MAOIs)
- decongestant cold or flu remedies containing pseudoephedrine or phenylpropanolamine
- medicines which may increase your blood pressure, such as dopamine or adrenaline
- food and drinks like mature cheese, yeast extracts, undistilled alcoholic drinks and fermented soya bean products such as soy sauce that contain high tyramine
- certain antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors)
- an antibiotic used for tuberculosis called rifampicin

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

ZYVOXID 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 ZYVOXID may react with a substance called tyramine which is naturally present in some foods to cause an increase in your blood pressure
- if you develop a throbbing headache after eating or drinking, tell your doctor or pharmacist immediately

Pregnancy and breastfeeding

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 receiving this medicine.

ZYVOXID should not be used if you are pregnant or breastfeeding.

You should not breastfeed if you are being given ZYVOXID because it passes into breast milk and could affect the baby.

Driving and using machines

No effects on the ability to drive and use machines have been observed.

It is not always possible to predict to what extent ZYVOXID 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 ZYVOXID affects them.

ZYVOXID Solution for infusion contains dextrose

Dextrose

ZYVOXID solution for infusion contains dextrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Each 1 mL of solution contains 45,7 mg glucose (13,7 g glucose in one 300 mL bag). Please tell your doctor or nurse if you are diabetic.

Sodium

Each 1 mL of solution contains 0,38 mg sodium (114 mg sodium in one 300 mL bag). Please tell your doctor or nurse if you are on a low sodium diet.

3. How to receive ZYVOXID

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

It is recommended that treatment with ZYVOXID begins in a hospital.

Your doctor will decide how ZYVOXID is given to you and what dose will be given.

Your doctor will decide on the duration of your treatment.

Adults and adolescents (12 years and older)

The usual dose is 600 mg IV every 12 hours depending on the type of infection.

Children (birth through to 11 years)

The usual dose is 10 mg/kg IV every 8 hours depending on the type of infection.

If you are on kidney dialysis, you should be given ZYVOXID after dialysis.

While you are receiving ZYVOXID, your doctor should perform regular blood tests to monitor your blood count.

Your doctor should monitor your eyesight if you receive ZYVOXID for more than 28 days.

Your doctor will tell you how long your treatment with ZYVOXID will last. Do not stop treatment early.

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

If you receive more ZYVOXID than you should

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

If you missed a dose of ZYVOXID

Since a health care provider will administer ZYVOXID solution for infusion, it is unlikely that the dose will be missed.

If you stop receiving ZYVOXID

Unless your doctor instructs you to stop treatment, it is important to continue receiving ZYVOXID.

If you stop and your original symptoms come back tell your doctor or pharmacist immediately.

4. Possible side effects

ZYVOXID can have side effects.

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

If any of the following happens, tell your doctor immediately:

- skin reactions such as red sore skin and flaking (dermatitis), rash, itching, or swelling, particularly around the face and neck called angioedema. This may be the sign of an anaphylactic allergic reaction, and it may be necessary for you to stop receiving ZYVOXID
- severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), which may develop into complications that are life-threatening
- recurrent nausea or vomiting, abdominal pain
- over-breathing
- seizures

These are all very serious side effects. If you have them, you may have had a serious reaction to ZYVOXID. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- fungal infections especially vaginal or oral “thrush”
- headache

- metallic taste in the mouth or alteration in taste
- stomach pain
- pain and cramps in the stomach or bloating due to gas
- diarrhoea, nausea or vomiting
- increased number of certain compounds (bilirubin, AST, ALT) in the blood that are high during liver damage
- increased number of enzymes (LDH, alkaline phosphatase, urea and creatinine, BUN, creatine kinase, lipase, amylase) that are high during certain diseases or organ damage
- increase in blood sugar (non-fasting)
- decrease in protein, albumin, sodium, calcium
- changes in the level of potassium or bicarbonate
- increased neutrophils or eosinophils
- decreased red blood cell count
- increased or decreased platelets

Less frequent side effects

- change in the number of certain types of blood cells
- increase in a type of enzyme called serum creatine phosphokinase
- high blood sugar
- dizziness, sensations such as tingling or feeling numb
- a reduced sense of touch
- difficulty in sleeping
- problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted
- ringing in the ears (tinnitus)
- increased blood pressure
- low blood pressure
- constipation
- dry or sore mouth
- indigestion

- stomach diseases
- feeling tired or thirsty
- inflammation of the pancreas (nausea, vomiting, fever/chills and abdominal (belly) pain)
- infection of the skin
- increased sweating
- skin rash and itching
- inflammation of the vagina or genital area in women
- a need to urinate more often
- fever or chills, aches and pains, fatigue or tiredness
- pain and inflammation of the veins (including where the infusion (drip) was given)
- increased creatinine, sodium and calcium
- decreased blood sugar
- increased or decreased chloride
- increased reticulocyte count (type of blood cell)
- decreased neutrophils (type of blood cell)
- Kidney failure
- Transient ischaemic attacks (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)

Other side effects

- 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
- build-up of lactic acid in the body
- convulsions
- damage to the nerve causing weakness, numbness and pain, usually in your hands and feet
- swollen, sore, or discoloured tongue
- superficial tooth discolouration, removable with professional dental cleaning (manual descaling)
- severe skin disorders like toxic epidermal necrolysis and Stevens-Johnson syndrome which results in painful blisters and peeling of the skin

- 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via 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 ZYVOXID.

You can report any suspected adverse drug reactions associated with the use of the medicine directly to Pfizer via ZAF.AEReporting@pfizer.com.

5. How to store ZYVOXID

Store all medicines out of reach of children.

Store at room temperature at or below 25 °C.

Infusion bags must be kept in overwrap until ready to use.

Protect from light.

Single-use infusion bags. Do not freeze.

Discard any unused solution.

6. Contents of the pack and other information

What ZYVOXID contains

The active substance is linezolid and belongs to the oxazolidinone class of antibiotics.

Each 1 mL of solution contains 2 mg linezolid. The 300 mL infusion bag contains 600 mg linezolid.

The other ingredients are citric acid anhydrous, dextrose monohydrate (a type of sugar), hydrochloric acid or sodium hydroxide, sodium citrate dihydrate and water for injections.

What ZYVOXID looks like and contents of the pack

A ready-to-use infusion bag containing a clear, colourless to yellow solution free of visible particles.

ZYVOXID Solution for infusion 600 mg/300 mL

Single-use infusion bags packaged in a foil overwrap available in a pack size of 300 mL (600 mg linezolid).

Holder of Certificate of Registration

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