

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ZYVOXID 20 mg/mL Granules for suspension

Linezolid

Contains sugar

ZYVOXID granules for suspension contains sugar (sucrose 1052,9 mg per 5 mL), fructose (500 mg/5 mL) and 35 mg per 5 mL of the sweetener aspartame.

Read all of this leaflet carefully before you start taking 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 take ZYVOXID
3. How to take 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 take ZYVOXID

Do not take ZYVOXID

- 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

Take special care with ZYVOXID:

- 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 take 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 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 taking 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 taking or after taking ZYVOXID. If this becomes severe or persistent or you notice that your stool contains blood or mucous, you should stop taking 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

- ZYVOXID suspension can be taken 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 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 taking this medicine.

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

You should not breastfeed if you have taken 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 Granules for suspension contains aspartame, sucrose and fructose.

Aspartame

Aspartame, a sweetening agent is partly converted into phenylalanine in the body. This may be harmful for people with phenylketonuria.

Sucrose and fructose

ZYVOXID granules for suspension contains sucrose and fructose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of fructose or galactose intolerance should not take ZYVOXID suspension.

Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take ZYVOXID granules for suspension.

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking ZYVOXID Suspension.

3. How to take ZYVOXID

Do not share medicines prescribed for you with any other person.

Always take ZYVOXID granules for suspension exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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 400 mg to 600 mg orally every 12 hours depending on the type of infection.

Children (birth through to 11 years)

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

If you are on kidney dialysis, you should take ZYVOXID after dialysis.

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

Your doctor should monitor your eyesight if you take 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 take more ZYVOXID than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you or somebody else takes too much oral liquid, tell your doctor or pharmacist immediately.

If you forget to take ZYVOXID Granules for suspension

Take the forgotten oral liquid as soon as you remember. Take the next dose 12 hours after this and continue taking the medicine every 12 hours.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking ZYVOXID

Unless your doctor instructs you to stop treatment, it is important to continue taking 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 taking ZYVOXID, please consult your health care provider for advice.

If any of the following happens, stop taking ZYVOXID and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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 taking 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
- 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.

Keep the bottle tightly closed and in the outer carton to protect from light.

Do not use after the expiry date printed on the carton.

Your suspension can be stored for three weeks at room temperature at or below 25 °C and should be used within 21 days.

Before use, gently turn the bottle upside down a few times.

Do not shake.

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 ZYVOXID contains

The active ingredient in this medicine is called linezolid and belongs to the oxazolidinone class of antibiotics.

Each 5 mL of suspension contains 100 mg linezolid.

Following reconstitution with 123 mL water, each 1 mL contains 20 mg linezolid. Preservative content: Sodium benzoate 0,2 % m/v.

The other ingredients are aspartame, carboxymethylcellulose sodium, citric acid anhydrous, colloidal silicon dioxide anhydrous, flavourings (orange, orange cream, peppermint, vanilla), mannitol, microcrystalline cellulose, sodium benzoate, sodium chloride, sodium citrate hydrous, sucrose, sweeteners (fructose, maltodextrin, monoammonium glycyrrhizinate and sorbitol), and xanthan gum.

What ZYVOXID looks like and contents of the pack

ZYVOXID Granules for suspension

A white to yellow-orange granule/powder, may contain white to yellow-orange lumps. The constituted suspension appears as a white to yellow-orange homogeneous suspension.

Granules for suspension in 240 mL amber glass bottles. Once mixed with water, the volume of suspension is 150 mL.

Holder of Certificate of Registration

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