

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM:

ZYVOXID 400 mg (Tablets)

ZYVOXID 600 mg (Tablets)

ZYVOXID 200 mg/100 ml (Solution for Infusion)

ZYVOXID 600 mg/300 ml (Solution for Infusion)

ZYVOXID 20 mg/ml (Granules for Suspension)

Linezolid

Read all of this leaflet carefully before you start using/are given ZYVOXID.

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

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.

1. WHAT ZYVOXID CONTAINS:

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

ZYVOXID 400 mg and ZYVOXID 600 mg Tablets: Each tablet contains 400 mg and 600 mg linezolid respectively. The other ingredients are microcrystalline cellulose, maize starch, sodium starch glycollate, hydroxypropylcellulose and magnesium stearate. The film coating contains opadry white and carnauba wax. The printing ink contains black iron oxide (400 mg tablets).

ZYVOXID 200 mg/100 ml and ZYVOXID 600 mg/300 ml Solution for Infusion: Each 1 ml of solution contains 2 mg linezolid. The other ingredients are glucose monohydrate (a type of sugar), sodium citrate, citric acid anhydrous, hydrochloric acid or sodium hydroxide and water for injections.

ZYVOXID 20 mg/ml Granules for Suspension: Each 5 ml of suspension contains 100 mg linezolid. The other ingredients xanthan gum, microcrystalline cellulose, carboxymethylcellulose sodium, anhydrous colloidal silica, sucrose, aspartame, mannitol, sweeteners (fructose, maltodextrin, monoammonium glycyrrhizinate, sorbitol), sodium benzoate, flavourings (orange, orange cream, peppermint, vanilla), sodium chloride, sodium citrate and citric acid anhydrous.

2. WHAT ZYVOXID 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.

3. BEFORE YOU USE/RECEIVE ZYVOXID:

You should not use/receive ZYVOXID if:

- you are allergic (hypersensitive) to linezolid or any of the other ingredients.
- you are taking or have taken within the last 2 weeks any medicines known as monoamine oxidase inhibitors (for example phenelzine, isocarboxazid, selegiline, moclobemide).
- 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 are not sure if you have any of these conditions.

- Do you have high blood pressure, whether or not you are taking medicines for this?
- Have you been diagnosed with an overactive thyroid?

- Do 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)?
 - Do you suffer from manic depression, schizoaffective disorder, mental confusion or other mental problems?
 - Are you taking any of the following medicines?
 - Decongestant, cold or flu remedies containing pseudoephedrine or phenylpropanolamine.
 - Medicines used to treat asthma such as salbutamol, terbutaline, fenoterol.
 - Antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors).
 - Medicines used to treat moderate to severe pain, such as pethidine.
 - Medicines used to treat anxiety disorders.
 - An antibiotic used for tuberculosis called rifampicin.

Take special care with ZYVOXID:

Tell your doctor before you are treated with ZYVOXID if you

- bruise and bleed easily.
- are anaemic (lack of iron in the blood / decreased numbers of red blood cells).
- have a history of seizures.
- have liver problems or kidney problems particularly if you have dialysis.
- have diarrhoea.

Tell your doctor immediately if during treatment you suffer from

- problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.
- recurrent nausea or vomiting, abdominal pain or over-breathing (lactic acidosis).

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.

Using ZYVOXID with food and drink:

- ZYVOXID Tablets and 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:

ZYVOXID should not be used if you are pregnant. Tell your doctor if you are pregnant, think you may be pregnant or are trying to become pregnant.

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

If you are pregnant or breast-feeding, ask your doctor or pharmacist for advice before using ZYVOXID.

Driving and using machinery:

ZYVOXID may make you feel dizzy. If this happens, do not drive or operate any machinery.

Important information about some of the ingredients in ZYVOXID Infusion

Glucose: 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.

Important information about some of the ingredients of ZYVOXID Suspension

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

Sucrose and fructose: Sucrose and fructose are sugars. If you have been told that you have an intolerance to some sugars contact your doctor before taking ZYVOXID.

Sodium: When made up into a suspension this medicine contains 51 mg of sodium per dose (8,5 mg per 5 ml). This should be taken into consideration if you are on a controlled sodium diet.

Using other medicines with ZYVOXID: 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.

Tell your doctor if you are taking or have taken within the last 2 weeks the following medicines as ZYVOXID **must not** be taken if you are already taking these medicines or have taken them recently.

- Monoamine oxidase inhibitors (MAOIs)

Also tell your doctor if you are taking the following medicines.

- 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, cipramil, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine, sertraline.

Medicines used to treat migraine

- Medicines used to treat moderate to severe pain, such as pethidine.
- Medicines used to treat anxiety disorders.
- Medicines that stop blood clotting, such as warfarin.

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

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ZYVOXID with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

4. HOW TO USE ZYVOXID:

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.

Children

ZYVOXID can be used in children and adolescents (under 18 years old).

If you think that the effect of ZYVOXID is too strong, or that it does not seem to be working, talk to your doctor or pharmacist.

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.

If you receive more ZYVOXID Infusion than you should:

Since ZYVOXID Infusion is given by a doctor or nurse, it is very unlikely that you will be given too much ZYVOXID.

If you take more ZYVOXID Tablets or Suspension than you should:

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

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

If you forget to take ZYVOXID Tablets or Suspension:

Take the forgotten tablet or 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 twice as much of the medicine to make up for the missing dose.**

Effects when treatment with ZYVOXID Tablets or Suspension is stopped:

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.

5. POSSIBLE SIDE EFFECTS:

ZYVOXID can cause side effects.

Tell your doctor, nurse or pharmacist immediately if you notice any of the following side effects during your treatment with ZYVOXID:

- skin reactions such as red sore skin and flaking (dermatitis), rash, itching, or swelling, particularly around the face and neck. This may be the sign of an allergic reaction and it may be necessary for you to stop taking ZYVOXID.
- problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.
- 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 or over-breathing. seizures have been reported with ZYVOXID. 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 side effects include:

Frequent side effects (likely to occur in less than 1 in 10 people):

- Fungal infections especially vaginal or oral “thrush”
- Headache
- Metallic taste in the mouth
- Diarrhoea, nausea or vomiting
- 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

Less frequent side effects (likely to occur in less than 1 in 100 people):

- Inflammation of the vagina or genital area in women
- Difficulty in sleeping
- Dizziness, sensations such as tingling or feeling numb
- Blurred vision
- “Ringing” in the ears (tinnitus)
- Increased blood pressure, inflammation of the veins
- Indigestion, stomach pain, constipation
- Dry or sore mouth, swollen, sore, or discoloured tongue
- Skin rash
- Pain and inflammation of the veins (including where the infusion (drip) was given)
- A need to urinate more often
- Fever or chills, aches and pains
- Feeling tired or thirsty
- Inflammation of the pancreas (nausea, vomiting, fever/chills and abdominal (belly) pain)
- Increased sweating
- 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)
- Severe skin disorders
- Convulsions
- Superficial tooth discolouration, removable with professional dental cleaning (manual descaling)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Not all side effects reported for ZYVOXID are included in this leaflet. Should your general health worsen while taking ZYVOXID, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF ZYVOXID:

Keep all medicines out of the reach and sight of children.

ZYVOXID Tablets: Store at room temperature below 25 °C. Tablets packed in plastic bottles must be stored in a dry place and protected from light. Do not use your tablets after the expiry date printed on the pack.

ZYVOXID Granules for Suspension: Store at room temperature 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 below 25 °C. 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).

7. PRESENTATION OF ZYVOXID:

ZYVOXID 400 mg Tablets: White plastic bottles of 10 or 30 tablets or blister strips of 10 or 30 tablets.

ZYVOXID 600 mg Tablets: White plastic bottles of 10 or 30 tablets or blister strips of 10 or 30 tablets.

ZYVOXID 200 mg/100 ml Solution for infusion: Single-use infusion bags packaged in a foil overwrap available in a pack size of 100 ml (200 mg linezolid).

ZYVOXID 600 mg/300 ml Solution for infusion: Single-use infusion bags packaged in a foil overwrap available in a pack size of 300 ml (600 mg linezolid).

ZYVOXID Granules for Suspension: Granules for suspension in 240 ml amber glass bottles. Once mixed with water, the volume of suspension is 150 ml.

8. IDENTIFICATION OF ZYVOXID:

ZYVOXID 400 mg Tablets: A white to off-white, oval-shaped tablet, marked on one side with “ZYVOXID 400 mg” in black ink.

ZYVOXID 600 mg Tablets: A white to off-white coated tablet with ‘ZYV’ debossed on one side and ‘600’ debossed on the other side.

ZYVOXID Solution for Infusion: A ready-to-use infusion bag containing a clear, colourless to yellow solution free of visible particles.

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.

9. REGISTRATION NUMBER:

ZYVOXID 400 mg Tablets: 35/20.1.1/0309

ZYVOXID 600 mg Tablets: 35/20.1.1/0310

ZYVOXID 20 mg/ml Granules for Suspension: 35/20.1.1/0311

ZYVOXID 200 mg/100 ml Solution for Infusion: 35/20.1.1/0312

ZYVOXID 600 mg/300 ml Solution for Infusion: 35/20.1.1/0313

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

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