

Package leaflet: Information for the user

ZYVOX[®] 100 mg/5 ml granules for oral suspension

Linezolid

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Zyvox is and what it is used for

Zyvox 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 Zyvox is suitable to treat your infection.

2. What you need to know before you take Zyvox

Do not take Zyvox:

- if you are allergic to linezolid or any of the other ingredients of this medicine (listed in section 6).
- if you are taking or have taken within the last 2 weeks any medicines known as monoamine oxidase inhibitors (MAOIs: for example phenelzine, isocarboxazid, selegiline, moclobemide). These medications may be used to treat depression or Parkinson's disease.
- if you are breast-feeding. This is because Zyvox passes into breast milk and could affect the baby.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Zyvox.

Zyvox 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 that another treatment is better for you.

Ask your doctor if you are not sure whether these categories apply to you.

- 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?

- Do you have a history of hyponatraemia (low blood sodium levels) or do you take medicines that lower blood sodium levels e.g. certain diuretics (also called “water tablets”) such as hydrochlorothiazide?
- Do you take any opioids?

The use of certain medicines, including antidepressants and opioids, together with Zyvox can lead to serotonin syndrome, a potentially life-threatening condition (see section 2 “Other medicines and Zyvox” and section 4).

Take special care with Zyvox

Tell your doctor before you take this medicine if you:

- are elderly
- bruise and bleed easily
- are anaemic (have low red blood cells)
- are prone to getting infections
- have a history of seizures
- have liver problems or kidney problems particularly if you are on 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.
- loss of sensitivity in your arms or legs or a sensation of tingling or pricking in your arms or legs.
- you may develop diarrhoea while taking or after taking antibiotics, including Zyvox. If this becomes severe or persistent or you notice that your stool contains blood or mucus, you should stop taking Zyvox immediately and consult your doctor. In this situation, you should not take medicines that stop or slow bowel movement.
- recurrent nausea or vomiting, abdominal pain or rapid breathing.
- feeling sick and unwell with muscle weakness, headache, confusion and memory impairment which may indicate hyponatraemia (low blood sodium levels).

Other medicines and Zyvox

There is a risk that Zyvox may sometimes interact with certain other medicines to cause side effects such as changes in blood pressure, temperature or heart rate.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

Tell your doctor if you are taking or have taken within the last 2 weeks the following medicines as Zyvox **must not** be taken if you are already taking these medicines or have taken them recently (see also Section 2 above ‘Do not take Zyvox’).

- 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 Zyvox, 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.
- Some medicines used to treat asthma such as salbutamol, terbutaline, fenoterol.

- 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.
- Opioids e.g., pethidine – used to treat moderate to severe pain.
- Medicines used to treat anxiety disorders, such as buspirone.
- Medicines that stop blood clotting, such as warfarin.
- An antibiotic called rifampicin.

Zyvox with food, drink and alcohol

- You can take Zyvox 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 Zyvox 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, breast-feeding and fertility

The effect of Zyvox in pregnant women is not known. Therefore, it should not be taken in pregnancy unless advised by your doctor. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not breast-feed when taking Zyvox because it passes into breast milk and could affect the baby.

Driving and using machines

Zyvox may make you feel dizzy or experience problems with your vision. If this happens, do not drive or operate any machinery. Remember that if you are unwell your ability to drive or operate machinery may be affected.

Zyvox contains

Aspartame

When made up into a suspension this medicine contains 210 mg aspartame in each dose, which is equivalent to 35 mg/5 ml. Aspartame is a source of phenylalanine. Phenylalanine may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Sucrose, sorbitol, mannitol and fructose

This medicine contains sucrose, mannitol, sorbitol and fructose.

When made up into a suspension this medicine contains no more than 100.8 mg fructose in each dose, which is equivalent to 16.8 mg/5 ml.

When made up into a suspension this medicine contains no more than 262.8 mg sorbitol in each dose, which is equivalent to 43.8 mg/5 ml. Sorbitol is a source of fructose.

If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Fructose may damage teeth when used frequently or over a long period of time (e.g. for two weeks or longer).

Due to its mannitol and sorbitol content, the oral suspension may have a mild laxative effect.

Sodium

When made up into a suspension this medicine contains 68.43 mg of sodium (main component of cooking/table salt) in each dose, which is equivalent to 11.4 mg per 5 ml. The amount of sodium per dose is equivalent to 3.4% of the recommended maximum daily dietary intake of sodium for an adult. This should be taken into consideration if you are on a controlled sodium diet.

Sodium benzoate

When made up into a suspension this medicine contains 60 mg sodium benzoate in each dose, which is equivalent to 10 mg/5ml. Sodium benzoate may increase levels of a substance called bilirubin. High levels of bilirubin may lead to jaundice (yellowing of the skin and eyes) and may also lead to brain injury (encephalopathy) in newborn babies (up to 4 weeks old).

Alcohol (ethanol)

When made up into a suspension this medicine contains no more than 6 mg alcohol (ethanol) in each dose, which is equivalent to 1 mg/5 ml (0.02% w/v). The amount of alcohol in each dose is equivalent to less than 0.15 ml beer or 0.06 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take Zyvox

Adults

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Zyvox comes as granules which will be made up exclusively by a healthcare professional to make a suspension for you to take.

The recommended dose of Zyvox suspension is six 5 ml spoonfuls (600 mg linezolid) twice daily (every 12 hours).

Before using, gently turn the bottle upside down a few times. **DO NOT SHAKE.**

If you are on kidney dialysis, you should take Zyvox 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 taking Zyvox, your doctor should perform regular blood tests to monitor your blood count.

Your doctor should monitor your eyesight if you take Zyvox for more than 28 days.

Use in children and adolescents

Zyvox is not normally used to treat children and adolescents (under 18 years old).

If you take more Zyvox than you should

Tell your doctor or pharmacist immediately.

If you forget to take Zyvox

Take the forgotten dose of medicine 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 a forgotten dose.

If you stop taking Zyvox

Unless your doctor instructs you to stop treatment, it is important to continue taking Zyvox.

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

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor, nurse or pharmacist immediately if you notice any of these side effects during your treatment with Zyvox:

The serious side effects (with frequency in brackets) of Zyvox are:

- Severe skin disorder (uncommon), swelling, particularly around the face and neck (uncommon), wheezing and/or difficulty breathing (rare). This may be the sign of an allergic reaction and it may be necessary for you to stop taking Zyvox. Skin reactions such as a raised purple rash due to inflammation of the blood vessels (rare), red sore skin and flaking (dermatitis) (uncommon), rash (common), itching (common).
- Problems with your vision (uncommon) such as blurred vision (uncommon), changes in colour vision (not known), difficulty in seeing detail (not known) or if your field of vision becomes restricted (rare).
- 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 (uncommon).
- Recurrent nausea or vomiting, abdominal pain or rapid breathing (rare).
- Fits or seizures (uncommon) have been reported with Zyvox.
- Serotonin syndrome (not known): You should let your doctor know if you experience agitation, confusion, delirium, rigidity, tremor, incoordination, seizure, rapid heartbeat, severe breathing problems, and diarrhoea (suggestive of serotonin syndrome) while also taking antidepressants known as SSRIs or opioids (see section 2).
- 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 (common).
- Changes in numbers of certain cells in the blood which may affect your ability to fight infection (uncommon) some signs of infection include: any fever (common), sore throat (uncommon), mouth ulcers (uncommon) and tiredness (uncommon).
- Inflammation of the pancreas (uncommon).
- Convulsions (uncommon).
- 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) (uncommon).
- “Ringing” in the ears (tinnitus) (uncommon).

Numbness, tingling or blurred vision have been reported by patients who have been given Zyvox for more than 28 days. If you experience difficulties with your vision you should consult your doctor as soon as possible.

Other side effects include:

Common (may affect up to 1 in 10 people):

- Fungal infections especially vaginal or oral “thrush”
- Headache
- Metallic taste in the mouth
- Diarrhoea, nausea or vomiting
- Changes in some blood test results including those measuring proteins, salts or enzymes which measure your kidney or liver function or blood sugar levels
- Difficulty in sleeping
- Increased blood pressure
- Anaemia (low red blood cell)
- Dizziness
- Localised or general abdominal pain
- Constipation
- Indigestion
- Localised pain
- Reduction in platelets

Uncommon (may affect up to 1 in 100 people):

- Inflammation of the vagina or genital area in women
- Sensations such as tingling or feeling numb
- Swollen, sore, or discoloured tongue
- Dry mouth
- A need to urinate more often
- Chills
- Feeling thirsty
- Increased sweating
- Hyponatraemia (low blood sodium levels)
- Kidney failure
- Abdominal bloating
- Increase in creatinine
- Stomach pain
- Changes in heart rate (e.g. increase rate)
- Decrease of the blood cell count
- Weakness and/or sensory changes

Rare (may affect up to 1 in 1,000 people):

- Superficial tooth discolouration, removable with professional dental cleaning (manual descaling)

The following side effects have also been reported (Not known: frequency cannot be estimated from the available data):

- Alopecia (hair loss)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

—HPRA Pharmacovigilance, ~~Earlsfort Terrace, IRL—Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.~~

Website: www.hpra.ie; E-mail: medsafety@hpra.ie

5. How to store Zyvox

Keep this medicine out of the sight and reach of children.

Keep the bottle in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

Any remaining, unused suspension should be discarded within 21 days of reconstitution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Zyvox contains

- The active substance is linezolid. After reconstitution each 5 ml of suspension contains 100 mg linezolid.
- The other ingredients are sucrose, mannitol, microcrystalline cellulose (E460), carboxymethylcellulose sodium (E466), aspartame, anhydrous colloidal silica (E551), sodium citrate, xanthan gum, sodium benzoate, citric acid anhydrous, sodium chloride, ethanol, and sweeteners (fructose, maltodextrin (corn derived), monoammonium glycyrrhizinate, sorbitol). Flavourings are orange flavour, peppermint flavour, vanilla flavour and orange cream flavour (see section 2 'Zyvox contains aspartame; sucrose, sorbitol, mannitol and fructose; sodium; sodium benzoate; and alcohol (ethanol)').

What Zyvox looks like and contents of the pack

Zyvox granules for oral suspension are supplied in a brown bottle containing a white to yellow-orange granule/powder, which may contain white to yellow-orange lumps or white to yellow-orange-brown lumps. The constituted orange flavoured liquid (suspension) appears as a white to yellow-orange liquid (suspension) when made up with water. Each bottle is packaged in a carton with a 2.5 ml/5 ml measuring spoon.

The Marketing Authorisation Holder

United Kingdom

The Marketing Authorisation Holder is Pfizer Limited, Sandwich, Kent, CT13 9NJ, UK

Ireland

The Marketing Authorisation Holder is Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, City West Business Campus, Dublin 24, Ireland: Telephone: 1800 633 363

Manufacturer

Pfizer Manufacturing Belgium NV, Rijksweg 12, B-2870 Puurs, Belgium or Pfizer Service Company BVBA, Hoge Wei 10, 1930 Zaventem, Belgium.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Zyvoxid
Belgium	Zyvoxid
Cyprus	Zyvoxid
Czech Republic	Zyvoxid
Denmark	Zyvoxid
Estonia	Zyvoxid
Finland	Zyvoxid
France	Zyvoxid
Germany	Zyvoxid
Greece	Zyvoxid
Iceland	Zyvoxid
Ireland	Zyvox
Italy	Zyvoxid
Latvia	Zyvoxid
Lithuania	Zyvoxid
Luxembourg	Zyvoxid
Malta	Zyvox
Netherlands	Zyvoxid
Norway	Zyvoxid
Poland	Zyvoxid
Portugal	Zyvoxid
Slovakia	Zyvoxid
Slovenia	Zyvoxid
Spain	Zyvoxid
Sweden	Zyvoxid
United Kingdom	Zyvox

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The following information is intended for healthcare professionals only:

Instructions for preparation of the oral suspension:

Linezolid comes as granules which will be made up exclusively by a healthcare professional.

Loosen the granules and reconstitute using 123 ml water in two approximately equal aliquots to produce 150 ml oral suspension. The suspension should be vigorously shaken between each addition of water. The appearance after reconstitution is a white to yellow-orange suspension.

Before using, gently turn the the bottle upside down a few times. **DO NOT SHAKE.**

The usual dose of Zyvox suspension is six 5 ml spoonfuls (600 mg linezolid) twice daily (every 12 hours).

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

See also Section 3 above 'How to take Zyvox'.