

Package leaflet: Information for the user

ZYVOX[®] 600 mg film-coated tablets 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
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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
- 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.
- 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 sodium

Zyvox contains less than 1 mmol sodium (23 mg) per 600 mg tablet, that is to say essentially 'sodium-free'.

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.

The recommended dose is one film-coated tablet (600 mg linezolid) twice daily (every twelve hours). Swallow the film-coated tablet whole with some water.

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 tablet as soon as you remember. Take the next film-coated tablet 12 hours after this and continue taking your film-coated tablets every 12 hours. Do not take a double dose to make up for a forgotten film-coated tablet.

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).
- 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.
- 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 or pharmacist. 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.

Ireland

HPRA Pharmacovigilance Website: www.hpra.ie

Malta

ADR Reporting Website:

www.medicinesauthority.gov.mt/adrportal

5. How to store Zyvox

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

Do not use this medicine after the expiry date which is stated on the pack or the blister after 'EXP'. The expiry date refers to the last day of that month. This medicinal product does not require any special storage conditions.

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 in this medicine is called linezolid. Each film-coated tablet contains 600 mg linezolid
-The other ingredients are maize starch (corn derived), microcrystalline cellulose (E460), hydroxypropylcellulose (E463), sodium starch glycolate type A (see section 2 'Zyvox contains sodium'), and magnesium stearate (E572). The *film coating* contains hypromellose (E464), titanium dioxide (E171), macrogol 400 and carnauba wax (E903).

What Zyvox looks like and contents of the pack

Zyvox 600 mg film-coated tablets are white, oval-shaped and debossed with "ZYV" on one side and "600" on the other.

Zyvox film-coated tablets are available in blister strips of 10 tablets packaged in a box.

Each box contains either 10, 20, 30, 50, 60 or 100 film-coated tablets. Also in white, HDPE bottle with a polypropylene screw cap containing either 10, 14, 20, 24, 30, 50, 60 or 100 (for hospital use only) film-coated tablets.

Not all pack sizes may be marketed.

The Marketing Authorisation Holder

MA Holder (Ireland):

Pfizer Healthcare Ireland Unlimited Company, The Watermarque Building, Ringsend Road, Dublin 4, D04 K7N3, Ireland. Telephone: 1800 633 363

MA Holder (Malta):

Pfizer Hellas S.A.
243 Messoghion Ave.
Neo Psychiko 15451
Greece

Manufacturer

Pfizer Manufacturing Deutschland GmbH
Mooswaldallee 1
79108 Freiburg Im Breisgau
Germany

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) 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 (Northern Ireland)	Zyvox

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