

ZYVOX[®] INJECTION

linezolid

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before taking Zyvox. This leaflet answers some common questions about Zyvox. It does not contain all the available information. It does not take the place of talking to your or your child's doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child taking Zyvox against the expected benefits it will have.

Ask the doctor if you have any concerns about you or your child taking this medicine.

Keep this leaflet even after your treatment with Zyvox is finished. You may need to read it again.

What Zyvox is used for

Zyvox contains the active ingredient, linezolid.

Zyvox is an antibiotic (an agent used to destroy certain types of bacteria). It is used in the treatment of bacterial infections such as pneumonia, skin infections or blood infections.

Depending on the type of bacteria, you may be given additional medicines.

Your doctor, however, may prescribe Zyvox for another purpose.

Ask your doctor if you have any questions about why Zyvox has been prescribed for you or your child.

This medicine is not addictive.

Before being treated with Zyvox

When Zyvox must not be given

Zyvox must not be given if you or your child:

- are allergic to linezolid or any of the other ingredients listed at the end of this leaflet.
Some of the symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.
- have uncontrolled high blood pressure
- have pheochromocytoma (a type of tumour of the adrenal gland)
- have thyrotoxicosis (an overactive thyroid gland)
- have flushing or other symptoms caused by a carcinoid tumour
- are taking or have taken in the last two weeks any medicine that is a monoamine oxidase inhibitor (e.g., moclobemide, phenelzine or tranylcypromine to treat depression or selegiline to treat Parkinson's disease)
- any cold or flu medicine containing pseudoephedrine
- adrenaline, a medicine used to treat severe allergic reactions
- any other medicine that increases blood pressure (e.g., noradrenaline, dopamine, dobutamine)
- are taking any medicine that is an SSRI or serotonin re-uptake inhibitor, which are types of medicine to treat depression, anxiety, panic attacks, obsessive-compulsive disorders or obesity (e.g., citalopram, escitalopram,

fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, sibutramine, venlafaxine)

- tricyclic antidepressants, which are medicines to treat depression (e.g., amitriptyline, clomipramine, dothiepin, doxepin, imipramine, nortriptyline, trimipramine)
- some medicines to treat migraine (e.g., naratriptan, sumatriptan, zolmitriptan)
- pethidine, a medicine to treat pain.
- buspirone, a medicine to treat anxiety

Before treatment with Zyvox

Tell the doctor if you or your child:

- have diarrhoea
- have allergies to any other medicines or substances, such as foods, preservatives or dyes
- are anaemic or have had any abnormal blood test results (e.g., low haemoglobin or platelets)
- are diabetic
Zyvox injection contains glucose.

Tell the doctor if you:

- are pregnant or planning to become pregnant
- are breastfeeding or intend to breastfeed.

If you are pregnant or breastfeeding, the doctor may decide not to prescribe Zyvox.

Talk to the doctor or pharmacist, if you have any concerns about you or your child being given Zyvox.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, tell the doctor if you or your child have been treated with or are taking:

- any medicine that inhibits monoamine oxidase (e.g., moclobemide, phenelzine or tranylcypromine to treat depression or selegiline to treat Parkinson's disease)
- any cold or flu medicine containing pseudoephedrine
- adrenaline, a medicine used to treat severe allergic reactions
- any other medicine that increases blood pressure (e.g., noradrenaline, dopamine, dobutamine)
- are taking any medicine that is an SSRI or serotonin re-uptake inhibitor, which are types of medicine to treat depression, anxiety, panic attacks, obsessive-compulsive disorders or obesity (e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, sibutramine, venlafaxine)
- tricyclic antidepressants, which are medicines to treat depression (e.g., amitriptyline, clomipramine, dothiepin, doxepin, imipramine, nortriptyline, trimipramine)
- some medicines to treat migraine (e.g., naratriptan, sumatriptan, zolmitriptan)
- pethidine, a medicine to treat pain.
- buspirone, a medicine to treat anxiety
- rifampicin, a medicine to treat tuberculosis and some other infections
- any medicine that could reduce the levels of haemoglobin (the pigment in red blood cells which carries oxygen) or platelets (blood cells which help blood to clot)

Ask the doctor or pharmacist if you are not sure about this list of medicines.

Also tell the doctor if your or your child's diet contains a lot of mature cheese, yeast extracts, meat extracts, soya bean extracts (e.g., soy sauce), draught beers or wine.

Zyvox may react with a substance which is naturally present in these foods.

How Zyvox is given

It is recommended that treatment with Zyvox begin in a hospital.

Zyvox will be given to you or your child by the doctor or nurse.

Zyvox is a liquid which is given by slow injection into the blood (known as an intravenous infusion or "drip").

If you or your child is on dialysis, Zyvox infusion should be given after dialysis.

You or your child may be changed from Zyvox injection to an oral preparation of Zyvox (such as tablets or oral suspension) to complete your course of treatment.

How much is given

The recommended dose for adults and adolescents 12 years and older is 600 mg twice daily (every 12 hours).

The recommended doses for babies and children up to 12 years of age is 10 mg/kg three times daily (every 8 hours).

These doses are given intravenously by a "drip" over a period of 30 to 120 minutes.

Treatment is usually given every day for 10 to 14 days, but may given for up to 28 days.

Ask the doctor if you want more information about the dose of Zyvox and how it is given.

In case of overdose

Overdose is unlikely as treatment will be given by the doctor or nurse. The possible effects of overdose are vomiting, tremors, unsteadiness or lack of coordination.

Tell the doctor or nurse immediately if you or your child have any of these effects or if you or your child feel worse during or after treatment with Zyvox.

While being treated with Zyvox

Things you must do

Follow all instructions given by the doctor.

In some cases, additional blood tests may be required.

As part of the treatment, you or your child may be given other medicines including other antibiotics. It is important to keep taking these medicines as well as Zyvox unless you are told otherwise by your doctor or pharmacist.

It is important to tell the doctor if you develop diarrhoea during or after treatment with Zyvox. Do this even if it occurs several weeks after Zyvox has been stopped.

Do not take any medicine to treat diarrhoea without first checking with the doctor.

Diarrhoea may be caused by a serious condition affecting the bowel. You or your child may need urgent medical care.

If you or your child get a sore white mouth or tongue during or soon after treatment with Zyvox tell your doctor.

Tell the doctor if you or your child get vaginal itching or discharge.

This may mean you or your child have a fungal infection called thrush. Sometimes the use of Zyvox allows fungi to grow which causes the symptoms described above. Zyvox does not work against fungi.

Things you must not do

Do not start taking any other medicines, prescription or not, without first telling your doctor or pharmacist.

Do not give your child any other medicines, prescription or purchased from a health food shop, pharmacy or supermarket without first telling your doctor or pharmacist.

Do not take any medicine to treat diarrhoea without first checking with the doctor.

Diarrhoea may be caused by a serious condition affecting the bowel. You or your child may need urgent medical care.

Avoid eating too much mature cheese, yeast extracts, meat extracts or soya bean extracts (e.g., soy sauce). Avoid drinking alcohol, especially draught beers and wine.

This is because Zyvox may react with a substance which is naturally present in these foods.

If you or your child develop a throbbing headache after eating, tell your doctor or health care professional.

Side effects

Tell the doctor or pharmacist as soon as possible if you or you child do not feel well while you are taking Zyvox.

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Do not be alarmed by the following lists of side effects.

You or your child may not experience any of them.

Ask the doctor or pharmacist to answer any questions you may have.

While taking it

Tell the doctor or pharmacist if you notice any of the following and they worry you:

- headache

- sore, white mouth or tongue (oral thrush)
- vaginal itching or discharge (vaginal thrush)
- pain, cramping or bloating of the abdomen
- nausea or vomiting
- metallic taste
- change in the colour of the tongue
- change in the colour of teeth. This may be reversible.

Tell your doctor immediately and before you or your child are given the next dose of Zyvox if you notice any of the following:

- skin reactions (hives, rash or itching)
- visual disturbances or numbness or weakness of the arms and legs (rare side effects that have been primarily reported in patients treated for longer than 28 days)
- tiredness, headaches, being short of breath when exercising, dizziness, looking pale, fever and chills, sore throat or bruising (these symptoms may indicate a decrease in the level of your blood cells)
- sweating, feeling drunk and dizzy, muscle twitching, fever and shivering, confusion
These may be symptoms of the serotonin syndrome, which is a rare but serious side effect.

If any of the following happen, tell your or your child's doctor immediately or go to Accident and Emergency at your nearest hospital:

- seizure
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, severe itching or hives or blisters on the skin.

These may be signs of a serious allergic reaction or side effect. You or your child may need urgent medical attention or hospitalisation. These side effects are rare.

After finishing it

Tell your or your child's doctor or pharmacist if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with Zyvox:

- severe stomach cramps
- watery and severe diarrhoea (which may be bloody), fever, in combination with one or both of the above.

Zyvox can cause some bacteria, which are normally present in the bowel and normally harmless, to multiply and therefore cause the above symptoms. You may need urgent medical attention.

Tell your or your child's doctor if you notice any other side effects. Other side effects not listed above may also occur in some people.

After using Zyvox

Storage

Zyvox will normally be stored in a hospital. It should be stored below 25°C and should be protected from light (kept in the box and foil wrapping before use).

Hospital staff will make sure the medicine is not used after the expiry date printed on the bag.

Product description

What Zyvox looks like

Zyvox injection is a sterile, clear, colourless to yellow fluid for injection supplied as 300 mL in infusion bags. Each bag is for single use only and is packaged in a foil overwrap contained within an outer carton.

Ingredients

The active ingredient in Zyvox is linezolid. There are 2 mg of linezolid in 1 mL of Zyvox.

Other ingredients are:

- glucose
- sodium citrate (E331)
- citric acid anhydrous (E330)
- hydrochloric acid (E507) / sodium hydroxide (E524) and
- water for injections.

Supplier

Zyvox is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Toll Free Number: 1800-675 229

It is supplied in New Zealand by:

Pfizer New Zealand Ltd

PO Box 3998

Auckland

Toll Free Number: 0800-736 363

Australian Registration Number

Zyvox can be identified by an Australian Register Number which is found on the box.

AUST R 79690 (600 mg/300 mL)

Date of preparation

This leaflet was revised in March 2010.

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