

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using Zyvox?

Zyvox contains the active ingredient linezolid. It is used in the treatment of bacterial infections such as pneumonia, skin infections or blood infections. For more information, see Section [1. Why am I using Zyvox?](#) in the full CMI.

### 2. What should I know before I use Zyvox?

Do not use if you or your child have ever had an allergic reaction to Zyvox or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use Zyvox?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Zyvox and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Zyvox?

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

Your doctor will give you instruction on how to take Zyvox tablets or oral suspension. You or your child may be changed from Zyvox injection to Zyvox tablets or oral suspension to complete the course of treatment.

More instructions can be found in Section [4. How do I use Zyvox?](#) in the full CMI.

### 5. What should I know while using Zyvox?

#### Things you should do

- Tell your doctor if the symptoms of the infection do not improve within a few days, or if they become worse; you or your child have severe diarrhoea, a sore white mouth or tongue;

	<p>you have vaginal itching or discharge; or if you are pregnant, or plan to become pregnant.</p> <ul style="list-style-type: none"> <li>● Tell any other doctor or dentist you visit that you or your child are using Zyvox.</li> <li>● For more information on "Things you should do" can be found in Section 5 in the full CMI.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not stop using this medicine or lower the dosage without checking with your doctor.</li> <li>● Do not use Zyvox to treat any other medical complaints unless your doctor tells you to.</li> <li>● Do not start taking any other medicines without first telling your doctor or pharmacist.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● Be careful driving or operating machinery until you know how Zyvox affects you.</li> <li>● This medicine may cause dizziness and visual impairment in</li> </ul>

	some people. Children should be careful performing activities requiring attention such as riding bicycles or climbing.
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Avoid drinking alcohol, especially draught beers and wine.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Zyvox injection is stored in the pharmacy or on the hospital ward at below 25°C.</li> <li>• Store Zyvox tablets or oral suspension in original carton at below 25°C until ready for use.</li> </ul>

For more information, see Section [5. What should I know while using Zyvox?](#) in the full CMI.

## 6. Are there any side effects?

Side effects of this medicine may include headache; sore white mouth or tongue; vaginal itching or discharge; abdominal pain or bloating; nausea; vomiting; metallic taste; change in colour of tongue or teeth; difficulty concentrating; memory or visual impairment; confusion; tiredness; dizziness; rash, itching or hives or blisters on skin; numbness or weakness of arms or legs; shortness of breath; sweating; seizure; fainting; coma; swelling

of face or lips; bleeding in lips, eyes, mouth, nose and genitals; painful red/purple spots with/without blisters and peeling of skin, may be accompanied by fevers, chills, aching muscles, dehydration, dark urine, reduced urine, no urine, joint pain, enlarged lymph nodes and generally feeling unwell.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Zyvox®

## linezolid

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### Consumer Medicine Information (CMI)

This leaflet provides important information about using Zyvox. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Zyvox.**

#### Where to find information in this leaflet:

- [1. Why am I using Zyvox?](#)
- [2. What should I know before I use Zyvox?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Zyvox?](#)
- [5. What should I know while using Zyvox?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Zyvox?

**Zyvox contains the active ingredient linezolid.** It 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 may have prescribed it for another reason. **Ask your doctor if you have any questions about why Zyvox has been prescribed for you or your child.**

## **2. What should I know before I use Zyvox?**

### **Warnings**

**Do not use Zyvox if you or your child have the following medical conditions:**

- allergic to linezolid, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

- uncontrolled high blood pressure
- pheochromocytoma (a type of tumour of the adrenal gland)
- thyrotoxicosis (an overactive thyroid gland)
- flushing or other symptoms caused by a carcinoid tumour.

## **Do not use Zyvox if you or your child are taking any of the following medicines:**

- 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 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)
- buspirone, a medicine to treat anxiety
- some medicines to treat migraine (e.g. naratriptan, sumatriptan, zolmitriptan)
- pethidine, a medicine to treat pain
- 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).

## **Do not use Zyvox if:**

- the packaging is torn or shows signs of tampering
- the expiry date printed on the pack has passed.



- **Zyvox oral suspension is more than 3 weeks since you received it from the pharmacist. If you are not sure whether you or your child should start taking this medicine, talk to your doctor.**

**Tell your doctor if you or your child have allergies to any other medicines, foods, preservatives or dyes.**

### **Tell your doctor if you or your child:**

- have diarrhoea
- have phenylketonuria
- are anaemic or have had any abnormal blood test results (e.g. low haemoglobin or platelets)
- are diabetic
- have kidney or liver problems.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

**Important information about some of the ingredients in Zyvox oral suspension which contains:**

- aspartame, which is partly converted into phenylalanine.
- sodium benzoate, which is known to be a mild irritant to the skin, eyes and mucous membranes. In the quantities present in Zyvox suspension (0.2%) no harmful effects are expected.
- sodium may be harmful in a low-sodium diet. Each mL contains sodium as sodium citrate dihydrate (3 mg), sodium benzoate (2 mg) and sodium chloride (2.7 mg).
- Each mL contains 210.6 mg sucrose, 100 mg mannitol (E421) and 7 mg aspartame (E951). Fructose and sorbitol (E420) are present in mafco magna sweet (12 mg) and sweet-am powder (6 mg).

Zyvox oral suspension is not suitable for treating people with hereditary fructose intolerance, glucose-galactose malabsorption syndrome or sucrase-isomaltase deficiency.

Sucrose may cause gastrointestinal complaints and diarrhoea.

**Zyvox injection contains glucose.**

Zyvox is not addictive.

### **3. What if I am taking other medicines?**

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

## **Some medicines and Zyvox may interfere with each other. These include:**

- any medicine that inhibits monoamine oxidase (e.g. moclobemide, phenelzine or tranylcypromine to treat depression or selegiline to treat Parkinson's disease)
- 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)
- buspirone, a medicine to treat anxiety
- some medicines to treat migraine (e.g. naratriptan, sumatriptan, zolmitriptan)
- any medicine that is an opioid, a medicine to treat pain
- 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)
- 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).

These medicines may be affected by Zyvox or may affect how well it works. You or your child may need different amounts of medicines, or may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

**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.

## **4. How do I use Zyvox?**

### **How much is given**

#### **Tablets**

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

#### **Oral suspension**

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

The recommended dose for adults and adolescents 12 years and older is 30 mL (600 mg) twice daily.

**Continue taking Zyvox until you or your child finish the tablets or oral suspension unless your doctor recommends otherwise.**

**Do not stop taking Zyvox unless your doctor tells you to, even if you feel better.**

**Do not stop giving Zyvox to your child unless your child's doctor tells you to, even if your child feels better.**

If you or your child do not complete the full course prescribed by the doctor, the bacteria causing the infection may continue to grow and multiply. The infection may not clear completely or it may return.

A course of treatment usually lasts 10 to 14 days but may be up to 28 days.

## **Injection**

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.**

## **How Zyvox is given**

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

### **Tablets and Oral Suspension**

Follow all directions given by your or your child's doctor carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask the doctor or pharmacist for help.

**Gently mix Zyvox oral suspension by slowly turning the bottle over a few times before you use it. DO NOT SHAKE THE BOTTLE.**

**Do not take or give Zyvox oral suspension to your child if it is more than 3 weeks since you received it from your pharmacist.**

### **Injection**

Zyvox injection 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").

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

## **When to take Zyvox**

Zyvox can be taken before, during or after meals.

**If you or your child is on dialysis, take Zyvox after dialysis.**

## **If you forget to take Zyvox**

Zyvox should be taken regularly at the same time each day. If you miss your dose at the usual time, ask your doctor or pharmacist for advice.

## **If you use too much Zyvox**

If you think that you or your child have used too much Zyvox, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

Symptoms of an overdose are vomiting, tremors (shaking), unsteadiness or lack of coordination.

## **5. What should I know while using Zyvox?**

### **Things you should do**

**If you or your child are about to be started on any new medicine, remind your doctor and pharmacist that you or your child are taking Zyvox.**

**Tell any other doctors, dentists and pharmacists who are treating you or your child that you are taking Zyvox.**

**If you or your child are going to have surgery, tell the surgeon or anaesthetist that you or your child are taking this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant while you are being treated with Zyvox, tell your doctor immediately.**

**Keep all of your doctor's appointments so that your or your child's progress can be checked.**

Your doctor may do some blood tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

**If the symptoms of the infection do not improve within a few days, or if they become worse, tell your or your child's doctor.**



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 should not do**

**Do not take Zyvox to treat other complaints unless your doctor tells you to do so.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

If you stop taking it suddenly, your condition may worsen.

**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.**

**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.**

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Zyvox affects you.**

This medicine may cause dizziness and visual impairment in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful performing activities requiring attention such as riding bicycles or climbing.

## **Drinking alcohol**

Avoid drinking alcohol, especially draught beers and wine.

## **Looking after your medicine**

**Keep your tablets or oral suspension in the original packaging, including outer carton, until it is time to take them. Keep oral suspension bottles tightly closed.**

If you take the medicine out of the pack it may not keep well.

**Keep Zyvox tablets and Zyvox oral suspension in a cool dry place where the temperature stays below 25°C.**

**Do not store Zyvox or any other medicines in a bathroom or near a sink.**

**Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep Zyvox where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Zyvox injection 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.

## **When to discard your medicine**

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

## **6. Are there any side effects?**

**Tell the doctor or pharmacist as soon as possible if you or your child do not feel well while you are being treated with Zyvox.**

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

You or your child may not experience any of them.

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>● headache</li><li>● sore, white mouth or tongue (oral thrush)</li><li>● vaginal itching or discharge (vaginal thrush)</li><li>● pain, cramping or bloating of the abdomen</li><li>● nausea or vomiting</li><li>● metallic taste</li><li>● change in the colour of the tongue</li><li>● change in the colour of teeth. This may be reversible</li><li>● difficulty concentrating, memory impairment, confusion, weakness and unsteadiness, which may lead to falls (these symptoms may indicate low sodium levels in the blood).</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• skin reactions (hives, rash or itching)</li><li>• 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)</li><li>• tiredness, headaches, being short of breath when exercising, dizziness, looking pale, dark circles around the eyes, fever and chills, sore throat or bruising (these symptoms may indicate a decrease in the level of your blood cells)</li><li>• sweating, feeling drunk and dizzy, muscle twitching, fever and shivering, confusion</li></ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>These may be symptoms of the serotonin syndrome, which is a rare but serious side effect.</p> <ul style="list-style-type: none"> <li>● seizure</li> <li>● hallucination</li> <li>● fainting</li> <li>● coma</li> <li>● shortness of breath</li> <li>● wheezing or difficulty breathing</li> <li>● swelling of the face, lips, tongue or other parts of the body</li> </ul>	

<b>Serious side effects (continued)</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● rash, severe itching or hives or blisters on the skin and bleeding in the lips, eyes, mouth, nose and genitals.</li> <li>● painful red/purple spots with/without blisters and peeling of skin. This may be accompanied by fevers and chills, aching muscles, joint</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects (continued)</b>	<b>What to do</b>
<p>pain, enlarged lymph nodes and generally feeling unwell</p> <ul style="list-style-type: none"> <li>● muscle aching or swelling</li> <li>● lack of consciousness</li> <li>● dehydration</li> <li>● dark red or brown urine, or reduced or no urine.</li> </ul>	

These are serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

## **After finishing Zyvox treatment**

**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 doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What Zyvox 600 mg tablet contains**

<b>Active ingredient</b>	linezolid
<b>Other ingredients</b>	The tablets also contain: <ul style="list-style-type: none"><li>● microcrystalline cellulose (E460i)</li><li>● maize starch</li></ul>

	<ul style="list-style-type: none"> <li>● sodium starch glycollate</li> <li>● hypromellose (E463)</li> <li>● magnesium stearate (E572).</li> </ul> <p>The film coating contains:</p> <ul style="list-style-type: none"> <li>● hypromellose (E464)</li> <li>● titanium dioxide (E171)</li> <li>● macrogol 400</li> <li>● carnauba wax (E903).</li> </ul>
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**What Zyvox Oral Suspension contains 20 mg/mL (total 150 mL) contains**

<b>Active ingredient</b>	linezolid
<b>Other ingredients</b>	<ul style="list-style-type: none"> <li>● sucrose</li> <li>● mannitol (E421)</li> <li>● microcrystalline cellulose (E460i)</li> <li>● carmellose sodium (E466)</li> <li>● aspartame (E951)</li> <li>● colloidal anhydrous silica (E551)</li> <li>● sodium citrate dihydrate (E331)</li> <li>● xanthan gum (E415)</li> <li>● sodium benzoate (E211)</li> </ul>

- citric acid (E330)
- sodium chloride.

The granules are flavoured with Mafco magnasweet, orange flavour, orange cream flavour, Sweet-am powder, vanilla flavour and peppermint flavour.

**For important information about some of the ingredients in Zyvox oral suspension, please see section [2 What should I know before I use Zyvox?](#)**

## **What Zyvox injection contains 2 mg/mL contains**

<b>Active ingredient</b>	linezolid
<b>Other ingredients</b>	<ul style="list-style-type: none"> <li>• glucose monohydrate</li> <li>• sodium citrate dihydrate (E331)</li> <li>• citric acid (E330)</li> <li>• hydrochloric acid (E507)/sodium hydroxide (E524)</li> <li>• water for injections.</li> </ul> <p>Each mL of Zyvox solution of injection contains 50.24 mg glucose monohydrate</p>

	and sodium as sodium citrate dihydrate (1.64 mg).
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**Do not take this medicine if you are allergic to any of these ingredients.**

## **What Zyvox looks like**

**Zyvox tablets:** white to off-white coated tablet with "ZYV" debossed on one side and "600" debossed on the other. The tablets are available in blister packs of 10 tablets.

AUST R 79694

**Zyvox oral suspension:** a white to yellow-orange fluid which is orange flavoured. It is supplied in an amber glass bottle with a screw cap. A measuring spoon with 2.5 mL and 5 mL markings is also provided.

AUST R 79695

**Zyvox injection:** 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.

AUST R 79690

## **Who distributes Zyvox**

Pfizer Australia Pty Ltd

Sydney, NSW

Toll Free Number: 1800 675 229.

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

This leaflet was prepared in October 2023.

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