

PACKAGE LEAFLET

Package leaflet: Information for the user

Zeldox 10 mg/ml oral suspension Ziprasidone

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Zeldox oral suspension is and what it is used for

Zeldox oral suspension belongs to a group of medicines called antipsychotics.

Zeldox oral suspension is used for the treatment of schizophrenia in adults - a mental disorder characterised by the following symptoms: to hear, see and feel things that do not exist, to believe in something not true, to feel unusual suspicions, to be absent and have difficulty in establishing social relationships, nervousness, depression or anxiety.

Zeldox oral suspension is also used for the treatment of manic or mixed episodes of moderate severity in bipolar disorder in adults and children and adolescents aged 10-17 years - a mental disorder characterised by alternate stages of euphoric (mania) or depressed mood states. During mania episodes, the most characteristic symptoms are: elated behaviour, exaggerated self-esteem, increase in energy, decreased need for sleep, lack of concentration or hyperactivity and repeated high risk-taking behaviour.

2. What you need to know before you use Zeldox oral suspension

Do not take Zeldox Oral Suspension

- if you are allergic to ziprasidone or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include; rash, itching, swelling in the face, or lips, difficulty in breathing.
- if you suffer or have suffered from heart problems or have recently had a heart attack.
- if you take medicines for heart rhythm problems or that may affect the heart's rhythm.

Also refer to the section “Other medicines and Zeldox Oral Suspension” below.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Zeldox Oral Suspension.

- if you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- If you have liver problems
- If you suffer or have suffered from seizure or epilepsy
- If you are elderly (over 65 years old) and suffer from dementia and are at risk of having a stroke
- if you have a low resting heart rate and/or you know that, you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)
- if you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate

Contact your doctor immediately if you experience any of the following:

- Severe skin reactions such as rash with blisters which could include ulcers in the mouth, skin shedding, fever and target-like spots on the skin that could be symptoms of Stevens-Johnson syndrome. These skin reactions could potentially be life-threatening.
- Zeldox oral suspension may cause sleepiness, fall in blood pressure when standing up, dizziness and gait disturbances, which may lead to falls. Caution should be taken, particularly if you are an elderly patient or have some debility.

Tell your doctor that you are taking Zeldox oral suspension before you have a laboratory test (such as blood, urine, liver function, heart rate etc) because it may alter the results of the test.

Children and adolescents

The safety and efficacy of ziprasidone in treatment of schizophrenia is not established in children.

Other medicines and Zeldox Oral Suspension

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

Do not take Zeldox Oral Suspension if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, such as:

- Class IA and III antiarrhythmics, arsenic trioxide, halofantrine, levomethadyl acetate, mesoridazine, thioridazine, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, dolasetron mesilate, mefloquine, sertindole or cisapride. These medicines affect the heart rhythm by prolonging the QT interval. If you have any further questions about this you should speak to your doctor.

Talk to your doctor or pharmacist before taking Zeldox Oral Suspension.

Please tell your doctor or pharmacist if you are taking or have recently taken medicines for the treatment of:

- bacterial infections; these medicines are known as antibiotics; e.g. macrolide antibiotics or rifampin;
- mood swings (ranging from depressive mood to euphoria), agitation and irritation; these are known as mood stabilising medicines e.g. lithium, carbamazepine, valproate;
- depression, including certain serotonergic medicines e.g. SSRI's such as fluoxetine, paroxetine, sertraline; or herbal medicines or natural remedies containing St John's Wort;
- epilepsy e.g. phenytoin, phenobarbital, carbamazepine, ethosuximide;
- Parkinson's disease e.g. levodopa, bromocriptine, ropinirol, pramipexole;

- or if you are taking or have recently taken the following medicines: verapamil, quinidine, itraconazole or ritonavir.

Also refer to the section “Do not take Zeldox Oral Suspension” above.

Zeldox Oral Suspension with food and drink

Zeldox oral suspension **MUST** be taken immediately **BEFORE OR JUST AFTER A MAIN MEAL**. Zeldox oral suspension must not be mixed or diluted with food or drink before administration, as this may increase the risk of side effects. Always use the syringe provided to take this medicine, and apply the oral suspension directly into the mouth.

You should not drink alcohol during treatment with this medicine, as this may increase the risk of side effects.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

You should not take Zeldox oral suspension during pregnancy unless you are told otherwise by your doctor because there is a risk that this medicine may harm your baby.

The following symptoms may occur in newborn babies, of mothers that have used Zeldox in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you need to contact your doctor.

Breast-feeding

Do not breast-feed if you are taking Zeldox oral suspension. This is because small amounts may pass into the mother’s milk.

Contraception

If you are able to become pregnant you should use an appropriate method of contraception when taking this medicine.

Driving and using machines

Taking Zeldox oral suspension may make you feel drowsy. If you experience this symptom you should not drive or use tools or machinery until the drowsiness disappears.

Zeldox Oral Suspension contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216)

This medicine contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (may possibly be delayed).

Zeldox Oral Suspension contains sodium

This medicine contains 4.66 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.23% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Zeldox oral suspension

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Zeldox oral suspension should be taken immediately before or just after a main meal. It must not be mixed or diluted with food or drink before administration. Always use the syringe provided to take this medicine.

Adults

Zeldox oral suspension should be taken twice daily, in the morning and in the evening. The recommended dose is 40-80 mg twice daily. You should try to take this medicine at the same time every day.

In long-term treatments, your doctor may adjust the dose. You should not exceed the maximum dose of 160 mg per day.

Children and adolescents with bipolar mania

The usual starting dose is 20 mg to be taken with a meal after which your doctor will advise on optimal doses for you. You should not exceed the maximum dose of 80 mg per day in children weighing 45 kg or less, or 160 mg per day in children weighing more than 45 kg.

The safety and efficacy of Zeldox in the treatment of schizophrenia in children and adolescents has not been established.

Elderly (over 65 years old)

If you are elderly your doctor will decide the suitable dose for you. Doses in those over 65 are sometimes lower than those used in younger people. Your doctor will advise you what the right dose is for you.

Patients with liver problems

If you have liver problems you will usually be given a lower dose of Zeldox oral suspension. Your doctor will work out the correct dose for you.

If you take more Zeldox Oral Suspension than you should

Contact your doctor or go to the nearest hospital casualty department immediately. Take your box of Zeldox oral suspension with you.

If you have taken too much Zeldox oral suspension, you may experience drowsiness, shaking, fits and uncontrollable movements of the head and neck.

If you forget to take Zeldox Oral Suspension

It is important you take Zeldox oral suspension regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just take your next dose. Do not take a double dose to make up for a forgotten dose.

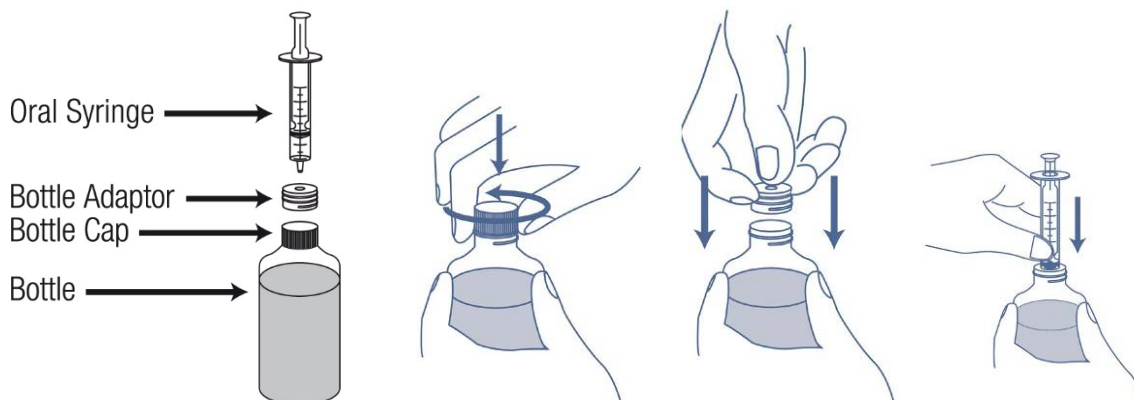
If you stop using Zeldox Oral Suspension

Your doctor will tell you how long to take Zeldox oral suspension for. You should not stop using this medicine, unless your doctor has told you to.

It is important to continue with your medication, even if you feel better. If you stop the treatment too early, the symptoms may return.

Instructions for use

Zeldox oral suspension should only be taken using the syringe for oral use included in the pack and should be administered directly into the mouth. Follow the instructions below for use of the syringe.



1. Shake the bottle before use. Open the childproof cap by pressing it down at the same time as you turn it counter or anti-clockwise.
2. A connection plunger for the syringe may have been connected to the bottleneck by the pharmacist. If not, press the connection plunger, which is included in the pack, down into the bottleneck.
3. Place the bottle upright on a firm and flat surface. Hold the bottle with one hand and with the other and introduce the tip of the syringe into the connection plunger.



4. Turn the bottle upside down while holding the syringe in place. Slowly, pull back the plunger of the syringe until the desired amount of medicine is withdrawn from the bottle. The syringe is graded (marked) in increments of 1ml (equivalent to 10mg). To measure the correct dose, the top of the black ring should be in line with the marking on the syringe indicating the desired dose.
5. If you see big bubbles in the syringe, slowly push the plunger back into the syringe. This will force the medicine back into the bottle. Repeat step 4 again.
6. Turn the bottle to the upright position, while the syringe is still in place. Then, remove the syringe.



7. Put the tip of the syringe in your mouth and SLOWLY push down the plunger. Do not squirt the medicine out quickly.

8. Screw the cap onto the bottle and leave in the connection plunger. Wash the syringe as described below.

How to clean and store the syringe

1. The syringe should be rinsed after each dose. Pull out the plunger from the syringe and wash both parts in warm soapy water and then rinse it under running water.

2. Dry both parts. Push the plunger back into the syringe. Store it in a clean and safe place, together with the medicine.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. However, most side effects are transient. It may often be difficult to distinguish the symptoms of your disease from those of side effects.

STOP taking Zeldox Oral Suspension and contact your doctor immediately if you experience any of the following serious side effects:

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

- Involuntary/unusual movements, especially in your face or tongue.

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

- Fast or irregular heartbeat, dizziness on standing up which may indicate abnormal functioning of the heart. These could be symptoms of a condition known as postural hypotension.

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

- Swelling in the face, lips, tongue or throat, swallowing or breathing problems, a nettle rash. These could be symptoms of a serious allergic reaction such as angioedema.
- Fever, faster breathing, sweating, muscle stiffness, shaking, difficulty swallowing and reduced consciousness. These could be symptoms of a condition known as neuroleptic malignant syndrome.
- Skin reactions, in particular rash, fever and swollen lymph nodes which could be symptoms of a condition called drug reaction with eosinophilia and systemic symptoms (DRESS). These reactions could be potentially life-threatening.

- Confusion, agitation, high temperature, sweating, lack of muscle co-ordination, muscle twitching. These could be symptoms of a condition known as serotonin syndrome.
- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.
- Persistent abnormal and painful erection of the penis.

You may experience any of the following side effects listed below. These potential side effects generally are mild to moderate and may resolve with time. However, if the side effect is severe or persistent, you should contact your doctor.

Very Common side effects (may affect more than 1 in 10 people):

- Difficulty sleeping
- Sleepiness or excessive daytime sleepiness
- Headache

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

- Runny nose
- High mood energy, strange thinking patterns and hyperactivity, feeling agitated or anxious
- Restlessness
- Abnormalities of movement including involuntary movements, muscular rigidity, slowness of movements
- Dizziness
- Sedation
- Blurred or impaired vision
- High blood pressure
- Constipation, diarrhoea, nausea, vomiting and indigestion, dry mouth, increased salivation
- Rash
- Male sexual problems
- Fever
- Pain
- Weight loss or gain
- Exhaustion
- General feeling of illness

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

- High levels of prolactin in the blood
- Increased appetite
- Panic attack
- Feeling nervous or depressed
- Decreased sexual desire
- Loss of consciousness
- Difficulty in controlling movements/involuntary movements
- Restless legs
- Throat tightness, nightmares
- Seizures, involuntary eyes movements into a fixed position, clumsiness, speech disorder, numbness, pins and needles sensation, reduced ability to concentrate, drooling
- Palpitation, breathlessness
- Sensitivity to light, dry eyes, buzzing in the ears, ear pain
- Sore throat, wind, stomach discomfort

- Itchy skin rash, acne
- Muscle cramp, stiff or swollen joints
- Thirst, chest discomfort, abnormal walk
- Acid reflux, stomach pain
- Hair loss
- Unusual position of head
- Urinary incontinence, pain or difficulty urinating
- Abnormal breast milk production
- Breast enlargement in men
- Absence of menstruation
- Abnormal heart or blood test results
- Abnormal liver function test results
- Vertigo
- General feeling of weakness and tiredness

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

- Decrease in calcium levels in the blood
- Slowed thinking, lack of emotions
- Facial droop
- Paralysis
- Partial or complete loss of vision in one eye, itchy eyes
- Difficulty speaking, hiccups
- Loose stools
- Skin irritations
- Inability to open mouth
- Difficulty emptying bladder
- Drug withdrawal syndrome in newborn babies
- Reduced orgasm
- Feeling hot
- Decrease or increase in white blood cells (in blood test)
- Patches of raised and inflamed red skin covered by a white scale known as psoriasis

Not known (frequency cannot be estimated from the available data):

- In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.
- Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.

Additional side effects in children and adolescents

In clinical trials with children and adolescents, the side effects were generally similar to adults (see above), except for sedation and sleepiness which were more often experienced by children. The most frequent side effects in children and adolescents were sedation, sleepiness, headache, exhaustion, nausea, dizziness, vomiting, decreased appetite and abnormalities of movement.

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 via [the national reporting](#)

system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zeldox oral suspension

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 carton. The expiry date refers to the last day of that month.

Once the bottle is opened, the medicine should be used within two months. Discard any unused medicine after this time.

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 Zeldox oral suspension contains

- The active substance is ziprasidone. Each ml contains 10mg ziprasidone as ziprasidone hydrochloride monohydrate. The other ingredients are: methylparahydroxybenzoate (E218), propylparahydroxybenzoate (E216) (see section 2 “Zeldox oral suspension contains methylparahydroxybenzoate (E218) and propylparahydroxybenzoate (E216)”), anhydrous citric acid (E330), sodium citrate (E331) (see section 2 “Zeldox oral suspension contains sodium”), sodium chloride (see section 2 “Zeldox oral suspension contains sodium”), xylitol (E967), xanthan gum (E415), polysorbate 80 (E433), anhydrous colloidal silica, cherry flavour and purified water.

What Zeldox looks like and contents of the pack

Zeldox oral suspension is a white to slightly yellow opaque suspension with cherry flavouring.

Pack sizes:

Plastic bottle with child-proof cap 60 ml.

Plastic oral syringe (8 ml) and press-in bottle adaptor. The 8 ml oral syringe is calibrated in 1.0 ml (10 mg) increments.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer

Mylan Hungary Kft., Mylan utca 1, Komárom 2900, Hungary

Viartis International Supply Point BV, Terhulpsesteenweg 6A, 1560 Hoeilaart, Belgium

This medicine is authorised in the Member States of the European Economic Area under the following names:

EU COUNTRIES	Oral Suspension
Austria, Denmark, Germany, Iceland, Norway, Portugal, Sweden	ZELDOX
Greece	GEODON

This leaflet was last revised in
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