

PACKAGE LEAFLET: INFORMATION FOR THE USER

ZELDOX

20 mg, 40 mg, 60 mg, 80 mg capsules, hard
ziprasidone

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Zeldox capsules are and what they are used for
2. Before you use Zeldox capsules
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1. WHAT ZELDOX CAPSULES ARE AND WHAT THEY ARE USED FOR

Zeldox capsules belong to a group of medicines called antipsychotics.

Zeldox capsules are 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 capsules are 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 sleeping, lack of concentration or hyperactivity and repeated high risk-taking behaviour.

2. BEFORE YOU USE ZELDOX CAPSULES

Do not take Zeldox Capsules

- if you are allergic (hypersensitive) to ziprasidone or any of the other ingredients of Zeldox capsules. 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 "Taking other medicines" below.

Take special care with Zeldox capsules

Check with your doctor **before** you use this medicine

- 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 seizures 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.

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription

DO NOT TAKE ZELDOX 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.

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 Capsules" above

Taking Zeldox capsules with food and drink

Zeldox capsules **MUST BE TAKEN DURING A MAIN MEAL.**

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

Pregnancy and breast-feeding

Pregnancy:

You should not take Zeldox capsules during pregnancy unless you are told otherwise by your doctor because there is a risk that this medicine may harm your baby. Always use effective contraception. Tell your doctor immediately if you become pregnant or are planning to become pregnant whilst taking Zeldox capsules.

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 may need to contact your doctor.

Breast-feeding:

Do not breast-feed if you are taking Zeldox capsules. This is because small amounts may pass into the mother's milk. If you are planning to breast-feed talk to your doctor before taking this medicine.

Ask your doctor or pharmacists for advice before taking any medicine.

Driving and using machines

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

Important information about some of the ingredients of Zeldox capsules

Zeldox capsules contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Zeldox capsules.

3. HOW TO USE ZELDOX CAPSULES

Always use Zeldox capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The capsules should be swallowed whole, not chewed and must be taken with meals. It is important not to chew the capsules as it may affect the extent to which the medicine is absorbed by the gut.

Zeldox capsules should be taken twice daily, one capsule in the morning during a full 'breakfast' and one in the evening during the 'evening meal' (see the blister pack). You should take this medicine at the same time every day.

Adults

The usual dose is 40-80 mg twice daily to be taken with meals.

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 may need to take a lower dose of Zeldox capsules. Your doctor will work out the correct dose for you.

If you take more Zeldox capsules than you should

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

If you have taken too many Zeldox capsules, you may experience drowsiness, shaking, fits and involuntary movements of the head and neck.

If you forget to take, Zeldox capsules

It is important you take Zeldox capsules 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 taking Zeldox capsules

Your doctor will tell you how long to take Zeldox capsules for. You should not stop using Zeldox, 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.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zeldox capsules 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 capsules and contact your doctor immediately if you experience any of the following serious side effects:

Uncommon side effects (affects 1 to 10 users in 1,000):

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

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

- 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.
- 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 heart beat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

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

Common side effects (affects 1 to 10 users in 100):

- Restlessness
- Abnormalities of movement including involuntary movements, muscular stiffness and rigidity, slowness of movements, shaking, general weakness and tiredness
- Sleepiness
- Headache
- Dizziness
- Constipation, nausea, vomiting and indigestion, dry mouth, increased salivation
- Blurred vision.

Uncommon side effects (affects 1 to 10 users in 1,000):

- Increased appetite
- Difficulty in controlling movements
- Feeling agitated or anxious, throat tightness, nightmares
- Seizures, involuntary eyes movements into a fixed position, clumsiness, speech disorder, numbness, pins and needles sensation, reduced ability to concentrate, drooling, excessive daytime sleepiness, exhaustion
- Palpitation, a feeling of faint when getting up, breathlessness
- Sensitivity to light, buzzing in the ears
- Sore throat, difficulty in swallowing, swollen tongue, diarrhoea, wind, stomach discomfort.
- Itchy skin rash, acne
- Muscle cramp, stiff or swollen joints
- Thirst, pain, chest discomfort, abnormal walk

Rare side effects (affects 1 to 10 users in 10,000):

- Runny nose
- Decrease in calcium levels in the blood
- Panic attack, feeling depressed, slowed thinking, lack of emotions
- Unusual position of head (Wry-neck or torticollis), paralysis, restless legs
- Partial or complete loss of vision in one eye, itchy eyes, dry eyes, vision disturbances
- Ear pain
- Hiccups
- Acid reflux
- Loose stools
- Hair loss, swelling of the face, skin irritations
- Inability to open mouth
- Urinary incontinence, pain or difficulty urinating
- Reduced or increased erection, reduced orgasm, abnormal breast milk production
- Breast enlargement in both men and women
- Feeling hot, fever
- Decrease or increase in white blood cells (in blood test)
- Abnormal liver function test results
- High blood pressure
- Abnormal blood, or heart rate test results
- 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):

- Serious allergic reaction
- 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.
- Difficulty sleeping, involuntary urinating
- Extremely high mood energy, strange thinking patterns and hyperactivity
- Loss of consciousness
- Large wheals (hives) with severe itching
- Persistent abnormal and painful erection of the penis
- Facial droop
- Drug withdrawal syndrome in newborn babies

If any of these side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

5. HOW TO STORE ZELDOX CAPSULES

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not use Zeldox capsules after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Zeldox capsules contain

- The active substance is ziprasidone. Each capsule contains 20mg, 40mg, 60mg or 80mg of ziprasidone as ziprasidone hydrochloride monohydrate.
- The other ingredients are: lactose monohydrate, pregelatinised maize starch, magnesium stearate, gelatin, titanium dioxide (E171), sodium laurilsulfate (sodium dodecylsulphate) and indigotin (E132) for capsules containing blue (20, 40 and 80 mg), shellac, ethyl alcohol anhydrous, isopropyl alcohol, n-butyl alcohol, propylene glycol, purified water, ammonium hydroxide, potassium hydroxide and black iron oxide (E172).

What Zeldox capsules look like and contents of the pack

Zeldox capsules are hard gelatin capsules.

Zeldox capsules 20 mg are blue/white and marked "Pfizer" and ZDX 20.

Zeldox capsules 40 mg are blue and marked "Pfizer" and ZDX 40.

Zeldox capsules 60 mg are white and marked "Pfizer" and ZDX 60.

Zeldox capsules 80 mg are blue/white and marked "Pfizer" and ZDX 80.

Pack sizes:

Aluminium PVC/PVA blisters containing 14, 20, 30, 50, 56, 60 or 100 capsules.

Plastic bottle (HDPE) with drying agent and child-proof screw cap containing 100 capsules.

A heat induction seal may be used as a closure, in which case no drying agent is included

Not all pack sizes may be marketed.

Marketing Authorisation Holder

INSERT LOCAL INFORMATION

Pfizer AB

191 90 Sollentuna

Sweden

Manufacturer:

R-Pharm Germany GmbH, Heinrich-Mack-Str. 35, 89257 Illertissen, Germany

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

EU COUNTRIES	Capsules
Austria, Denmark, Finland, Germany, Iceland, Italy, Norway, Portugal, Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia	ZELDOX
Ireland	GEODON
Greece, Spain, Sweden	ZELDOX, GEODON

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