

PACKAGE LEAFLET

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 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 capsules are and what they are used for
2. What you need to know before you use Zeldox capsules
3. How to take Zeldox capsules
4. Possible side effects
5. How to store Zeldox capsules
6. Contents of the pack and other information

1. What Zeldox Capsules are and what are they 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. What you need to know before you use Zeldox Capsules

Do not take Zeldox Capsules

- 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 Capsules" below.

Warnings and precautions

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

- 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 capsules 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 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.

Children and adolescents

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

Other medicines and Zeldox Capsules

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 capsules 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 Capsules.

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.

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

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

Zeldox capsules contain lactose

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.

Zeldox capsules contains sodium

Zeldox capsules contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Zeldox Capsules

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

Capsules should be taken with food and swallowed whole without chewing, crushing or opening beforehand. It is important not to chew, crush or open 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 recommended 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 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 capsules 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 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 Capsules

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

Do not store above 30°C.

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.

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 capsules contains

- The active substance is ziprasidone. Each capsule contains 20 mg, 40 mg, 60 mg or 80 mg of ziprasidone as ziprasidone hydrochloride monohydrate.
- The other ingredients are: lactose monohydrate (see section 2 “Zeldox capsules contain lactose”), pregelatinised maize starch, magnesium stearate, gelatin, titanium dioxide (E171), sodium laurilsulfate (sodium dodecylsulphate) (see section 2 “Zeldox capsules contain sodium”) and indigotin (E132) for capsules containing blue (20, 40 and 80 mg), shellac, propylene glycol (E1520), ammonium hydroxide (E527), potassium hydroxide (E525) and black iron oxide (E172).

What Zeldox capsules looks like and contents of the pack

Zeldox capsules are hard gelatin capsules.

Zeldox capsules 20 mg are blue/white and marked “VTRS” and ZDX 20.

Zeldox capsules 40 mg are blue and marked “VTRS” and ZDX 40.

Zeldox capsules 60 mg are white and marked “VTRS” and ZDX 60.

Zeldox capsules 80 mg are blue/white and marked “VTRS” and ZDX 80.

Pack sizes:

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer:

Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79108 Freiburg Im Breisgau, Germany

or

MEDIS INTERNATIONAL a.s., výrobní závod Bolatice

Průmyslová 961/16

747 23 Bolatice

Czech Republic

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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