

PACKAGE LEAFLET

Package leaflet: Information for the user

Zeldox **20 mg/ml powder for solution for injection** Ziprasidone

Read all of this leaflet carefully before you start using 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 and will be given to you by a doctor or nurse.
- 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. 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 Injection is and what it is used for
2. What you need to know before you use Zeldox Injection
3. How to use Zeldox Injection
4. Possible side effects
5. How to store Zeldox Injection
6. Contents of the pack and other information

1. What Zeldox Injection is and what it is used for

Zeldox belongs to a group of medicines called antipsychotics.

Zeldox for injection is used to quickly control agitation (anxiety) in 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 for injection can be used for a maximum of three consecutive days.

2. What you need to know before you use Zeldox Injection

You may have been given Zeldox in an emergency so you may be reading this leaflet after having been given it. Your doctor will have considered the following points but check them yourself in case you need to be given Zeldox again.

Do not use Zeldox

- 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 use medicines for heart rhythm problems or that may affect the heart's rhythm.

Also refer to the section "Other medicines and Zeldox Injection" below.

Warnings and precautions

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

- 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 Injection 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 having Zeldox 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

Children and adolescents under the age of 18 should not be given Zeldox for injection.

Other medicines and Zeldox Injection

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines, including medicines obtained without a prescription.

Do not use Zeldox Injection if you use 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 Injection

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

- skin and fungal infections such as ketoconazole;
- 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. Selective serotonin reuptake inhibitors (SSRI's) such as fluoxetine, paroxetine, sertraline;
- epilepsy e.g. phenytoin, phenobarbital, carbamazepine, ethosuximide;
- Parkinson's disease e.g. levodopa, bromocriptine, ropinirol, pramipexole.

Also refer to the section "Do not use Zeldox" above.

Taking Zeldox with food and drink

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

Do not use Zeldox 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 antipsychotics 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 should contact your doctor.

Breast-feeding

Do not breast-feed if you are using Zeldox. 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 may make you feel drowsy after receiving this medicine. If you experience this symptom, do not drive or use tools or machinery until the drowsiness disappears.

Zeldox Injection contains sodium.

This medicinal product contains less than 1 mmol sodium (23 mg) per each ml of reconstituted solution for injection and therefore is essentially sodium-free.

3. How to use Zeldox Injection

Adults

Zeldox for injection is given into a muscle. Your doctor or pharmacist will decide how much medicine you should receive. The recommended dose is 10 mg but some people may need 20 mg as their first dose. If the dose of your first injection is 10 mg, you may be given another injection two hours later. If your first dose is 20 mg, you may be given another injection four hours later.

Your doctor may adjust the amount of medicine you are given so that your symptoms are adequately controlled.

Zeldox for injection will be given to you for a maximum of three consecutive days.

If you need further treatment your doctor may decide to continue your treatment using Zeldox capsules or Zeldox oral suspension.

Zeldox must not be injected into a blood vessel.

Children and adolescents

Children and adolescents under the age of 18 should not be given Zeldox for injection.

Elderly (over 65 years old)

The use of Zeldox is not recommended.

Patients with liver problems

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

Patients with kidney problems

Tell your doctor if you have kidney problems as this may affect the dose your doctor prescribes for you.

If you think you have been given more Zeldox than you should

If you think you have been given more medicine than you should, inform your doctor or nurse immediately.

If you have received too much of this medicine, you may experience drowsiness, shaking, fits, feeling more anxious and uncontrollable movements of the head and neck.

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

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 using Zeldox and contact your doctor immediately if you experience any of the following serious side effects:

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.
- Involuntary/unusual movements, especially in your face or tongue.
- A persistent abnormal and painful erection of the penis.

Not known (frequency cannot be estimated from the 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.
- 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.

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.

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

- difficulty in sleeping
- feeling agitated or anxious
- restlessness
- abnormalities of movement including muscular rigidity, slowness of movements and shaking
- sleepiness
- headache
- dizziness
- high blood pressure
- low blood pressure
- nausea, vomiting
- constipation
- dry mouth

- feeling weak and or loss of strength
- burning sensation and/or pain at the site of injection
- increased tiredness

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

- decreased appetite
- increased difficulty in social relationships, seeing or hearing things that are not there
- mania (extremely high mood energy, strange thinking patterns and hyperactivity)
- difficulty in controlling movements or making involuntary sounds such as throat clearing, sniffing, or grunting, difficulty and/or not being able to move parts of your body, clumsiness
- loss of consciousness
- speech disorder
- slow heart rate
- loss of balance, light-headedness
- feeling flushed
- stomach problems such as diarrhoea
- increased and/or excessive sweating
- rash
- having flu-like illness
- discomfort, redness at the injection site
- drug withdrawal syndrome
- increase in liver enzymes

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

- urinary incontinence, pain or difficulty urinating

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

- facial droop/sagging of the face
- 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
- involuntary urination
- drug withdrawal syndrome in new born babies
- abnormal breast milk production

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 Injection

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

Do not store above 30°C. Keep the container in the outer carton.

Do not use this medicine after the expiry date, which is stated on the carton and vial after EXP. 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 for injection contains

- The active substance is ziprasidone. Each vial contains 20 mg ziprasidone as ziprasidone mesilate.
- The other ingredient is sulphobutyl ether beta-cyclodextrin sodium (see section 2 “Zeldox Injection contains sodium”).

What Zeldox looks like and contents of the pack

Zeldox for injection is provided as a white to off-white powder for solution for injection. Each carton contains 1 vial (powder).

The vials are made of flint glass, sealed with rubber stoppers and flip-off aluminium seals.

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer

Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Pocé-sur-Cisse, France.

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

EU COUNTRIES	INTRAMUSCULAR
Austria, Denmark, Finland, Germany, Iceland, Italy, Portugal, Spain, Sweden	ZELDOX
Greece	GEODON

This leaflet was last revised in 2023-05-02

<[To be completed nationally]>

Health Care Professional: Please read and detach before handing leaflet to patient.

**METHOD OF PREPARATION AND ADMINISTRATION OF ZELDOX 20 mg/ml POWDER
FOR SOLUTION FOR INJECTION**

Preparation

- Aseptic technique must be used for the preparation of the final intramuscular solution as no preservative or bacteriostatic agent is included in the product.
- Each vial of ZELDOX powder should be reconstituted by the introduction of 1.2 ml water for injection solvent to achieve a final concentration of 20 mg ziprasidone per ml and shaking for approx 1/2 - 1 minute until all the contents have completely dissolved.
- Only water for injection solvent should be used to reconstitute ZELDOX 20 mg/ml Injection.
- As the vials are for single use only, any unused portion of the solution should be discarded.
- Prior to administration, carefully inspect the vial visually for particles and discoloration. Discard vials containing discoloured solution or visible particulate matter.

Administration

- Withdraw the appropriate volume (0.5 or 1 ml) of solution from the vial of reconstituted solution and administer by intramuscular injection.

Compatibility and Stability

- Additives or other medication should not be added to ZELDOX 20 mg/ml Injection. If ZELDOX 20 mg/ml Injection is to be given at the same time as another drug, each drug should be given separately according to the manufacturer's recommended dosage and route of administration.
- ZELDOX 20 mg/ml Injection has been shown to be stable after reconstitution for up to 24 hours at 25°C or for up to 7 days when refrigerated at 2 - 8°C.
- After reconstitution, the solution should be protected from light and from a microbiological point of view should be used immediately.
- When reconstituted as directed, a fill volume of 1.5 ml is created (50% overfill) containing a total of 30 mg ziprasidone. This overfill facilitates the withdrawal of 1 ml to provide 20 mg of ziprasidone.
- After withdrawal of the dose, discard any unused solution.
- Do not store above 30°C.
- Keep the container in the outer carton.