

PATIENT INFORMATION LEAFLET
ZOXADON RANGE

SCHEDULING STATUS:

S5

PROPRIETARY NAME AND DOSAGE FORM:

ZOXADON 0,5 mg: Each tablet contains 0,5 mg risperidone.

ZOXADON 1 mg: Each tablet contains 1 mg risperidone.

ZOXADON 2 mg: Each tablet contains 2 mg risperidone.

ZOXADON 3 mg: Each tablet contains 3 mg risperidone.

ZOXADON 4 mg: Each tablet contains 4 mg risperidone.

ZOXADON 6 mg: Each tablet contains 6 mg risperidone.

Please read this leaflet carefully before taking ZOXADON tablets

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor or your pharmacist.

ZOXADON has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT ZOXADON CONTAINS

The active substance: Risperidone

The other ingredients are: microcrystalline cellulose, lactose anhydrous, magnesium stearate, Opadry white or yellow, and pregelatinised starch.

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Contains sugar in the form of lactose anhydrous (61,70 mg in 0,5 mg tablet; 61,25 mg in 1 mg tablet; 122,50 mg in 2 mg tablet; 183,75 mg in 3 mg tablet; 245 mg in 4 mg tablet and 367,50 mg in 6 mg tablet).

2. WHAT ZOXADON IS USED FOR

Risperidone is an atypical antipsychotic.

ZOXADON is indicated for:

- Acute and chronic schizophrenia (where you may see, hear or feel things that are not there, believe things that are not true or feel unusually suspicious or confused) and related psychosis in which positive symptoms and/or the negative symptoms are prominent
- Mania, where you may feel very excited, elated, agitated, enthusiastic or hyperactive. Mania occurs in an illness called 'bipolar disorder'
- Conduct and other disruptive behaviour disorders in children (aged 5 -12 years), with subaverage intellectual functioning or mental retardation in whom destructive behaviours are prominent.

3. BEFORE YOU TAKE ZOXADON

Do not take ZOXADON:

- If you are hypersensitive (allergic) to risperidone or any of the other ingredients of ZOXADON (see **WHAT ZOXADON CONTAINS**).
- If you are elderly with dementia
- If you are pregnant or breastfeeding
- If you are under 5 years with conduct and other disruptive behaviour disorders

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- If you have Parkinson's disease (muscle weakness, muscle stiffness, impaired and slow movement and shaking)
- If you have Lewy body dementia (a form of progressive dementia).

Take special care with ZOXADON:

Tell your doctor:

- If you are taking furosemide tablets
- If you have a history of cerebrovascular adverse events: strokes
- If you suffer from heart disease or have low blood pressure
- If your doctor has told you that you have a low white blood cell count
- If you or someone else in your family has a history of blood clots, as ZOXADON has been associated with formation of blood clots
- If you suffer from kidney or liver function impairment.
- If you suffer from Parkinson's disease. ZOXADON may worsen the symptoms of this conditions
- If you have a condition called tardive dyskinesia: characterised by jaw movements, chewing-like movements, tongue movements, smacking of the lips or involuntary rapid arm or leg movements.
- If you experience any of the following symptoms of neuroleptic malignant syndrome (NMS): muscle spasms, irregular pulse or blood pressure, high fever, irregular heart rate, increased heart rate and increased sweating (perspiration)

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- If you suffer from epilepsy: fits / seizures. ZOXADON may worsen the symptoms of this condition
- If you have diabetes: high blood sugar
- If you experience any of the following: excessive or inappropriate production or breastmilk, enlargement of a man's breasts, disturbances in the menstrual cycle
- If you experience persistent and painful erections of the penis
- If you have problems controlling your body temperature or over heating
- If you are [old aged] elderly or suffer from dementia (progressive intellectual impairment) associated with Parkinsonism
- If you are planning to have an eye operation, intraoperative floppy iris syndrome may increase the risk of eye complications during and after cataract surgery
- If you have a tendency to gain weight easily

Taking ZOXADON with food and drink

ZOXADON can be taken with or without food.

Do not take alcohol and ZOXADON simultaneously.

Pregnancy and Breastfeeding:

The safety of ZOXADON in pregnant and breastfeeding women has not yet been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking ZOXADON.

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ZOXADON may cause sleepiness and a lack of concentration. Do not drive or operate any machinery before you know how ZOXADON affects you.

Important information about some of the ingredients of ZOXADON:

ZOXADON contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ZOXADON.

ZOXADON contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Using other medicines with ZOXADON:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Consult your doctor or pharmacist before taking other centrally acting medicines (e.g. sleeping tablets).

It is especially important to talk to your doctor or pharmacist if you are taking any of the following:

- Medicines that work on your brain such as to help you calm down (benzodiazepines) or some medicines for pain (opiates), medicines for allergy (some antihistamines), as risperidone may increase the sedative effect of all of these
- Medicines that may change the electrical activity of your heart, such as medicines for malaria, heart rhythm problems, allergies (antihistamines), some antidepressants or other medicines for mental problems

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- Medicines that cause a slow heartbeat
- Medicines that cause low blood potassium (such as certain diuretics)
- Medicines to treat raised blood pressure. ZOXADON can lower blood pressure
- Medicines for Parkinson's disease (such as levodopa)
- Medicines that increase the activity of the central nervous system (psychostimulants, such as methylphenidate)
- Water tablets (diuretics) used for heart problems or swelling of parts of your body due to a build-up of too much fluid (such as furosemide or chlorothiazide). ZOXADON taken by itself or with furosemide, may have an increased risk of stroke or death in elderly people with dementia.

The following medicines may reduce the effect of ZOXADON

- Rifampicin (a medicine for treating some infections)
- Carbamazepine, phenytoin (medicines for epilepsy).

If you start or stop taking such medicines, you may need a different dose of ZOXADON.

The following medicines may increase the effect of ZOXADON

- Quinidine (used for certain types of heart disease)
- Antidepressants such as paroxetine, fluoxetine, tricyclic antidepressants
- Medicines known as beta-blockers (used to treat high blood pressure)
- Phenothiazines (such as medicines used to treat psychosis or to calm down)
- Cimetidine, ranitidine (blockers of the acidity of stomach)

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- Itraconazole and ketoconazole (medicines for treating fungal infections)
- Certain medicines used in the treatment of HIV/AIDS, such as ritonavir
- Verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm
- Sertraline and fluvoxamine, medicines used to treat depression and other psychiatric disorders.

If you start or stop taking such medicines, you may need a different dose of ZOXADON. If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using ZOXADON.

4. HOW TO TAKE ZOXADON

Do not share medicines prescribed for you with any other person.

Always take ZOXADON exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of ZOXADON is too strong or too weak, talk to your doctor or pharmacist.

Treatment of schizophrenia

If you are already using an antipsychotic medicine, your doctor may gradually discontinue this treatment when switching to ZOXADON. If you are receiving a depot injection, your doctor will initiate ZOXADON treatment in place of the next scheduled injection.

You may take ZOXADON either once daily or twice daily.

Initial adult dose: The usual dose is 2 mg per day. Your doctor may increase the dosage to 4 mg per day on the second day.

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Maintenance dose: Your doctor will decide what the optimum maintenance dose is based on your response. The usual maintenance dose is 4 mg to 8 mg daily, but your doctor may increase the total dose up to 16 mg per day.

Treatment for mania in bipolar disorders

Initial adult dose: the usual starting dose is 2 or 3 mg once daily.

Maintenance dose: your doctor may decide to increase your dosage, based on your response. The usual maintenance dose is 1 – 6 mg daily.

Elderly patients and patients with kidney or liver problems

The starting dose is usually 0,5 mg twice daily. Your doctor may increase the dose up to 1 - 2 mg twice daily.

Treatment of conduct and other disruptive behaviour disorders in children 5 - 12 years of age

The usual starting dose is 0,01 mg per kg once daily. The doctor may increase the dose to a maintenance dose of 0,02- 0,04 mg per kg once daily.

If you take more ZOXADON than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take a dose of ZOXADON:

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If you missed a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the tablet at the usual time. Do not take a double or larger dose to make up for the forgotten individual doses. If you have trouble remembering when to take ZOXADON, ask your pharmacist for some hints.

5. POSSIBLE SIDE EFFECTS

ZOXADON can have side effects. Not all side effects reported for ZOXADON are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZOXADON, please consult your healthcare provider for advice.

If any of the following happens, stop taking ZOXADON and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- yellowing of the skin and eyes, also called jaundice

These are all very serious side effects. If you have them, you may have had a serious reaction to ZOXADON. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fast or irregular heartbeat
- difficulty or unusually fast breathing, shortness of breath, chest pain

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- wheezing, irregular blood pressure, high fever, sweating
- life-threatening complications of uncontrolled diabetes (high blood sugar)
- muscle stiffness or tightness, loss of sensation on one or both sides of body, loss of consciousness

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Pneumonia, infection of the chest (bronchitis), common cold symptoms, sinus infection, urinary tract infection, ear infection, feeling like you have the flu
- Weight gain, increased appetite, decreased appetite
- Sleep disorder, irritability, depression, anxiety, restlessness
- Involuntary movements of muscles, the eyes, mouth, tongue or jaw (dystonia)
- Dizziness, shaking
- Blurred vision, conjunctivitis (or pink eye)
- High blood pressure
- Sore throat, cough, nose bleeds, stuffy nose
- Abdominal pain or discomfort, vomiting, nausea, constipation, diarrhea, indigestion dry mouth, toothache
- Muscle spasms, bone or muscle ache, back pain, joint pain
- Incontinence (lack of control) of urine
- Fall

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Less frequent side effects:

- Infection of the breathing passages, pneumonia bladder infection, 'eye infection, fungal infection of the nails, infection of the skin
- Anemia, decrease in red/white blood cells
- Diabetes or worsening of diabetes, high blood sugar, excessive drinking of water
- Confusion (or change in mental state), sleep related eating disorder
- Tardive dyskinesia (twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body), disturbance in attention, lack of taste
- Oversensitivity of the eyes to light, dry eye, increased tears, redness of the eyes
- Vertigo, ringing in the ears, ear pain
- Low blood pressure
- Stomach or intestinal infection, stool incontinence, very hard stool, difficulty swallowing, excessive passing of gas or wind
- Hives, itching, hair loss, eczema, dry skin, skin discoloration, acne
- Joint swelling, muscle weakness, neck pain
- Frequent urination, pain when passing urine
- Erectile dysfunction, ejaculation disorder, breast swelling in men, menstrual disorders, vaginal discharge, decrease in sexual desire
- Decreased body temperature, coldness in arms and legs

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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6. STORING AND DISPOSING OF ZOXADON

- Store at or below 25 °C.
- For tablets in blisters: Keep the blisters in the carton until required for use.
- For tablets in containers: Keep well closed in the original container.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

- Do not use the tablets after the expiry date printed on the blister/container
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).