**PATIENT INFORMATION LEAFLET**

**ZOXADON RANGE**

**SCHEDULING STATUS**

S5

**ZOXADON 0,5 mg** tablets

**ZOXADON 1 mg** tablets

**ZOXADON 2 mg** tablets

**ZOXADON 3 mg** tablets

**ZOXADON 4 mg** tablets

Risperidone

ZOXADON contains sugar (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 and 245 mg in 4 mg tablet.

**Read all of this leaflet carefully before you start taking ZOXADON**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- 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.

**What is in this leaflet**


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

## 1. What ZOXADON is and what it 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, decreased need for sleep, pressured speech, racing thoughts, distractibility, or poor judgment including disruptive or aggressive behaviours. Mania occurs in an illness called 'bipolar disorder'
- conduct and other disruptive behaviour disorders in children (aged 5 -12 years), with sub-average intellectual functioning or mental retardation in whom destructive behaviours are prominent.

## 2. What you need to know before you take ZOXADON

**Do not take ZOXADON:**

- if you are hypersensitive (allergic) to risperidone, or to any of the other ingredients of ZOXADON (listed in section 6)
- Do not give this medicine to children under 5 years with conduct and other disruptive behaviour disorders
- 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).

**Warnings and precautions**

Take special care with ZOXADON:

Tell your doctor:

- if you know of any factors which would increase your chance of you having a stroke, such as high blood pressure, cardiovascular disorder, or blood vessel problems in the brain

- if you suffer from heart disease (examples include an irregular heart rhythm) or if you have low blood pressure or if you are taking furosemide (medicine for your blood pressure). ZOXADON can cause low blood pressure. Your dose needs to be adjusted
- if your doctor has told you that you have a low white blood cell count. Your doctor may check your white blood cell counts during therapy
- 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 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 are taking a medicine called methylphenidate together with ZOXADON, as this combination may increase the risk of unwanted side effects
- 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)
- if you suffer from Parkinson's disease. ZOXADON may worsen the symptoms of these conditions
- if you suffer from epilepsy: fits/seizures. ZOXADON may worsen the symptoms of these conditions
- if you have diabetes: high blood sugar. As diabetes mellitus or worsening of pre-existing diabetes mellitus has been seen in patients taking ZOXADON, your doctor should check for signs of high blood sugar. In patients with pre-existing diabetes mellitus, blood glucose should be monitored regularly
- if you have a tendency to gain weight easily
- if you experience any of the following: excessive or inappropriate production of breastmilk, enlargement of a man’s breasts, disturbances in the menstrual cycle
- if you experience persistent and painful erections of the penis
- you have problems controlling your body temperature or overheating

- 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 suffer from kidney or liver function impairment.

**Elderly people with dementia:**

In elderly patients with dementia, there is an increased risk of stroke. You should not take ZOXADON if you have dementia caused by stroke.

During treatment with ZOXADON you should frequently see your doctor.

Medical treatment should be sought straight away if your caregiver notices a sudden change in your mental state or sudden weakness or numbness of your face, arms, or legs, especially on one side, or slurred speech, even for a short period of time.

Studies in elderly patients with dementia have shown that ZOXADON taken by itself or with furosemide, is associated with a higher rate of death. Tell your doctor if you are taking furosemide. Furosemide is a medicine which is sometimes used to treat high blood pressure, some heart problems or to treat swelling of parts of the body caused by the build-up of too much fluid.

**Children and adolescents**

Children and adolescents under 15 years should not be treated with ZOXADON for schizophrenia or mania. Before treatment is started for conduct disorder, other causes of aggressive behaviour should have been ruled out. If during treatment with ZOXADON tiredness occurs, a change in the time of administration might improve attention difficulties. Before treatment is started your, or your child's body weight may be measured, and it may be regularly monitored during treatment. For the treatment of conduct disorder, the doctor will prescribe the suitable dose and treatment duration according to the patient's weight. Children under 5 years should not be treated with ZOXADON for conduct disorder. A small and inconclusive study has reported an increase in height in children who took ZOXADON, but whether this is an effect of the medicine or due to some other reason is not known.

**Other medicines and ZOXADON**

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

**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
- Do not take alcohol as this may make you sleepy
- Medicines for Parkinson's disease (such as levodopa), as ZOXADON may cause these medicines to be less effective
- Medicines to treat raised blood pressure. ZOXADON can lower blood pressure
- 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
- Paliperidone (used to treat schizophrenia) is not recommended for use with ZOXADON.

**The following medicines may reduce the effect of ZOXADON**

- Rifampicin (a medicine for treating some infections)
- Carbamazepine, phenytoin medicine mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face), may change the effect of ZOXADON. Therefore, inform your doctor if

you start or stop taking carbamazepine

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
- Sertraline and fluvoxamine, medicines used to treat depression and other psychiatric disorders
- Medicines known as beta blockers (used to treat high blood pressure)
- Phenothiazines (such as medicines used to treat psychosis or to calm down)
- Cimetidine and ranitidine, two medicines used to reduce stomach acid, may slightly increase the level of ZOXADON in your blood, but they are unlikely to change the effect of ZOXADON
- Itraconazole and ketoconazole (medicines for treating fungal infections)
- ZOXADON can enhance the effect of medicines that reduce the ability to react (e.g., tranquilisers, narcotic painkillers, certain antihistamines, certain antidepressants), only take these medicines if your doctor prescribes them
- 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.

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.

**ZOXADON with food, drink, and alcohol**

Refer to section 3. ZOXADON can enhance the effects of alcohol, so do not drink alcohol whilst taking ZOXADON.

**Pregnancy, breastfeeding, and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before taking this medicine.

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

If you are pregnant or if you are planning to become pregnant, you should inform your doctor, who will decide if you can take ZOXADON. Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding, have been observed in newborns, if a mother used ZOXADON in the last trimester of her pregnancy.

Do not breastfeed if you are taking ZOXADON.

ZOXADON can raise your levels of a hormone called prolactin that may impact fertility (see Possible side effects).

**Driving and using machines**

ZOXADON may cause vision problems, sleepiness, and a lack of concentration. Do not drive or operate any machinery before you know how this medicine affects you. It is not always possible to predict to what extent ZOXADON may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZOXADON affects them.

**Zoxadon contains lactose anhydrous**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ZOXADON. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ZOXADON. ZOXADON contains lactose anhydrous which may have an effect on the control of your blood sugar if you have diabetes mellitus.

**3. How to take ZOXADON**

Do not share medicines prescribed for you with any other person. Always use ZOXADON exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

**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.

**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.

**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.

**Children:**

Not suitable for the treatment of schizophrenia in children under the age of 15. For children older than 15, doses similar to that for adults may be administered.

**Treatment for mania in bipolar disorders**

**Initial adult dose:** The usual dose is 2 mg or 3 mg per day.

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

**Use in children and adolescents**

Children and adolescents under 18 years old should not be treated with ZOXADON for bipolar mania.

**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 by 0,01 mg/kg every other day, if needed, to a maintenance dose of 0,02 - 0,04 mg per kg once daily.

Your doctor will tell you how long your treatment with ZOXADON will last. Do not stop treatment early because your symptoms may return.
If you have the impression that the effect of ZOXADON is too strong or too weak, tell your doctor or pharmacist.

**If you take more ZOXADON than you should**

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

Symptoms of overdose may include:

- feeling sleepy or tired, abnormal body movements, problems standing and walking, feel dizzy due to low blood pressure, or have abnormal heartbeats.

**If you forget to take ZOXADON**

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 forgotten individual doses. If you have trouble remembering when to use your medicine, ask your pharmacist for some hints

**If you stop taking ZOXADON**

You should not stop taking ZOXADON unless told to do so by your doctor. Your symptoms may return. If your doctor decides to stop ZOXADON, your dose may be decreased gradually over a few days.

## 4. 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 using ZOXADON, please consult your healthcare provider for advice.

If any of the following happens, stop using 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.

These are all very serious side effects. If you have them, you may have had a serious allergic 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:

- swelling, pain, and redness in the leg, difficulty breathing, tight chest, discoloured lips – signs of a blood clot in the leg or lungs
- dangerously lowered white blood cell count that leads to severe infection (agranulocytosis) with symptoms that may include fever and chills, muscle weakness and fatigue, low blood pressure (feeling dizzy), ulcers in the mouth or throat
- a condition that causes the body to retain water and certain levels of electrolytes in the blood to fall (such as sodium)
- dangerously excessive intake of water
- life threatening complications of uncontrolled diabetes (high blood sugar)

- confusion (or change in mental state), depression, staying still, fast, or strange movements, difficulty in expressing emotions, manic episodes
- neuroleptic malignant syndrome (confusion, reduced or loss of consciousness, high fever, and severe muscle stiffness or tightness), loss of sensation on one or both sides of the body, loss of consciousness, convulsions (fits), abnormal coordination or balance, restlessness or need to keep moving, change in attention level, absence of reflex action normally induced by touch or pain, loss of balance
- blood vessel problems in the brain, stroke (trouble walking, speaking, and understanding, as well as paralysis or numbness of the face, arm, or leg), lack of speech and other unusual behaviour (catatonia)
- Parkinsonism: This condition may include slow or impaired movement, sensation of stiffness or tightness of the muscles (making your movements jerky), and sometimes even a sensation of movement freezing up and then restarting. Other signs of parkinsonism include a slow shuffling walk, a tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face
- fast or irregular heartbeat, palpitations
- yellowing of the skin and eyes, also called jaundice
- muscle injury where the muscles break down (rhabdomyolysis) with symptoms that may include muscle pain in the shoulders, thighs, or lower back; muscle weakness or trouble moving arms and legs; and dark red or brown urine or decreased urination
- problems in urination – specifically inability to pass urine or passing less urine than is normal for you.

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, urinary tract infection, feeling like you have the flu

- increased levels of a hormone called prolactin found on a blood test (which may or may not cause symptoms, common symptoms may include breast swelling in men, difficulty in getting or maintaining erections, or other sexual dysfunction; breast discomfort, leakage of milk from the breasts, missed or other problems with menstrual periods in women
- weight gain, increased appetite, decreased appetite
- insomnia, sleep disorders, depression, anxiety, agitation
- dizziness, sleepiness, headache, drowsiness, muscle quivering, restlessness, and inability to sit still, involuntary movements of muscles, the eyes, mouth, tongue, or jaw (dystonia), tremors
- blurred vision
- high blood pressure
- breathing difficulty, sore throat, cough, nose bleeds, stuffy nose
- abdominal pain or discomfort, vomiting, nausea, constipation, diarrhoea, indigestion dry mouth, toothache
- skin rash or itching
- muscle spasms, bone or muscle ache, back pain, joint pain
- incontinence (lack of control of urine)
- general swelling, fever, chest pain, asthenia (general weakness), fatigue, swelling in your lower legs or hands
- fall.

Less frequent side effects:

- sinusitis, ear infection, chest infection, bladder infection, eye infection, tonsillitis, ear infection, fungal infection in the nails, infection of the skin, viral infections
- abnormal blood test results, anaemia, decrease in red/white blood cells
- glucose present in the urine (determined through urine tests)
- anorexia, excess thirst, high blood sugar levels (hyperglycaemia), weight loss

- decreased libido, nervousness, nightmares, delayed, infrequent or absent orgasms
- 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
- dizziness when standing up, slurred speech, numbness, tingling or pricking sensation (pins and needles), increased duration of sleep, speech disorder, uncontrollable nodding of your head, diabetic coma, movement disorder (problems with physical coordination, trouble walking, episodes of uncontrolled movements, muscle weakness, twitching, or muscle spasm), pacing around the room, tapping your toes, or rapid talking
- changes in vision, pink eye, eye oversensitivity to light, dry eye, eye watering (increased tears), red eyes, eye movement disorder, dilation pupils or glaucoma (high eye pressure), eye rolling, eye discharge and eyelid crusting, eye swelling
- vertigo, ringing in the ears, ear pain
- low blood pressure, drop in blood pressure when standing up, flushing
- pneumonia caused by inhaling food, lung congestion, congestion of breathing passages, crackly lung sounds, wheezing, voice disorder, breathing passage disorder, hyperventilation
- stomach or intestinal infection, stool incontinence, very hard stool, difficulty swallowing, excessive passing of gas or wind, swollen tongue, lip swelling
- increased liver transaminases in your blood, increased GGT (a liver enzyme called gamma-glutamyl transferase) in your blood, increased liver enzymes in your blood
- hives (nettle rash), itching, thickening of skin, eczema, dry skin, skin discolouration, acne, dandruff, skin disorder, skin lesion, painless swelling under the skin
- an increase of CPK (creatine phosphokinase) in your blood, an enzyme which is sometimes released with muscle breakdown
- abnormal posture, joint stiffness, joint swelling, muscle weakness, neck pain
- frequent urination or increase in amount of urine, pain when passing urine
- sexual dysfunction (erectile and ejaculation dysfunction), menstrual disorders, abnormal absence

of menstruation, unusual secretion of milk; breast enlargement in men, milky nipple discharge, breast discomfort, enlargement, pain or engorgement, vaginal discharge, decreased sexual desire

- swollen or puffy face, chills, increased or decreased body temperature, coldness in arms and legs, abnormal gait (change in the way you walk), thirst, chest discomfort, general feeling of discomfort, illness, or unease, discomfort, drug withdrawal symptoms, hardening of the skin, flu-like sickness, sluggishness
- procedural pain.

The following side effects have been reported but the frequency for them to occur is not known:

- diabetes or worsening of diabetes, increased cholesterol, low blood sugar, blood triglycerides (a type of fat) increased
- mania (mental illness marked by periods of great excitement or euphoria, delusions, and over activity)
- sleep walking, sleep related eating disorder, altered taste
- eye problems during cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you take or have taken ZOXADON. If you need to have cataract surgery, be sure to tell your eye doctor if you take or have taken ZOXADON
- irregular heart rhythm that can be seen on an electrocardiogram (extended interval between the heart contracting and relaxing)
- sleep apnoea (a potentially serious sleep disorder in which breathing repeatedly stops and starts)
- intestinal obstruction, pancreatitis (inflammation of the pancreas with symptoms including abdominal pain, nausea, vomiting), paralytic ileus (occurs when the muscle contractions that move food through your intestines are temporarily paralyzed)
- hair loss
- neonatal drug withdrawal syndrome
- prolonged and painful erection of the penis

- hypothermia (an abnormally, typically dangerously low body temperature).

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

**Reporting of side effects**

If you get side effects, talk to your doctor,pharmacist or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8 or http://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/.

By reporting side effects, you can help provide more information on the safety of ZOXADON. You can also send an email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

**5. How to store ZOXADON**

Store all medicines out of reach of children.

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.

Do not store in a bathroom.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

**6. Contents of the pack and other information**

**What ZOXADON contains:**

The active substance is risperidone.

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

ZOXADON 1 mg tablets: Each tablet contains 1 mg risperidone.

ZOXADON 2 mg tablets: Each tablet contains 2 mg risperidone.

ZOXADON 3 mg tablets: Each tablet contains 3 mg risperidone.

ZOXADON 4 mg tablets: Each tablet contains 4 mg risperidone.

The other ingredients are:

Core: Lactose anhydrous, magnesium stearate, microcrystalline cellulose, pregelatinised starch.

Coating [Opadry white 03F28470 (1/2/3/4 mg) or Opadry yellow 03F32566 (0,5 mg)]: Hypromellose 6, macrogol 6000, titanium dioxide, iron oxide yellow (0,5 mg only)

**What ZOXADON looks like and contents of the pack**

ZOXADON 0,5 mg: Light yellow, oval, biconvex, scored, film coated tablets, marked T. Size 8 x 5 mm

ZOXADON 1 mg: White, oval, biconvex, scored, film coated tablets, marked T1. Size 8 x 5 mm

ZOXADON 2 mg: White, oval, biconvex, scored, film coated tablets, marked T2. Size 10 x 5 mm

ZOXADON 3 mg: White, oval, biconvex, scored, film coated tablets, marked T3. Size 11 x 6,5 mm

ZOXADON 4 mg: White, oval, biconvex, scored, film coated tablets, marked T4. Size 14 x 7,5 mm

ZOXADON is packed into transparent PVC-PVDC/Al heat sealed blisters.

ZOXADON is also packed into HDPE containers with a snap-on LDPE cap with a tamper evident ring.

Pack size: 20 or 30 tablets. Not all pack sizes may be marketed.

**Holder of Certificate of Registration**

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

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ZOXADON 1 mg: A41/2.6.5/0445

ZOXADON 2 mg: A41/2.6.5/0446

ZOXADON 3 mg: A41/2.6.5/0469

ZOXADON 4 mg: A41/2.6.5/0470

**NAMIBIA:**

NS3 ZOXADON 0,5 mg: 10/2.6.5/0021

NS3 ZOXADON 1 mg: 10/2.6.5/0022

NS3 ZOXADON 2 mg: 10/2.6.5/0023