PATIENT INFORMATION LEAFLET

ZOXADON ODT RANGE

SCHEDULING STATUS

S5

ZOXADON ODT 0,5 mg orodispersible tablets

ZOXADON ODT 1 mg orodispersible tablets

ZOXADON ODT 2 mg orodispersible tablets

Risperidone

ZOXADON ODT contains sweetener (aspartame) in the following quantities: 0,4 mg, 0,8 mg, and 1,6 mg g per 0,5 mg, 1 mg and 2 mg tablet, respectively.

ZOXADON ODT contains sugar (mannitol 27,8 mg, 55,6 mg and 111,2 mg per 0,5 mg, 1 mg and 2 mg tablet, respectively).

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

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

PATIENT INFORMATION LEAFLET

ZOXADON ODT RANGE

1. What ZOXADON ODT is and what it is used for

ZOXADON ODT contains risperidone, one of a group of medicines called antipsychotic.

ZOXADON ODT is used for:

- schizophrenia: where you may see, hear, or feel things that are not there, have problems thinking clearly, managing your emotions, relating to others and functioning normally, you may suffer from delusions, hostility, suspicion, emotional numbness, emotional and social withdrawal, and have problems communicating. ZOXADON ODT can help alleviate the symptoms of your condition and stop your symptoms from coming back.
- behavioural problems in children (aged 5 -12 years), with below average intellectual functioning or mental retardation – such as aggression, impulsiveness and self-harm. The weight of the child should be 50 kg and above in order to take ZOXADON ODT
- mania in bipolar disorder. These episodes are characterised by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility, or poor judgment, including disruptive or aggressive behaviours.

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

Do not take ZOXADON ODT:

- if you are hypersensitive (allergic) to risperidone, or to any of the ingredients of ZOXADON ODT (see section 6)
- if you are pregnant or breastfeeding (see Pregnancy and breastfeeding)
- if you have Lewy body dementia (a type of dementia related to Alzheimer's disease) or Parkinson's disease
- do not give ZOXADON ODT to children under 5 years with conduct and other disruptive behaviour disorders.

Warnings and precautions

Take special care with ZOXADON ODT:

- if you have been diagnosed with dementia associated with Parkinson's disease and senile dementia (see Do not take ZOXADON ODT)
- if you are currently taking furosemide (to treat high blood pressure and swelling caused by excess fluid in the body) as there may be an increased risk of severe dehydration or death in elderly people with dementia
- if you have kidney problems (signs include nausea, vomiting, loss of appetite, extreme tiredness, weakness, sleep problems, change in how much you urinate
- if you have liver problems (signs include abdominal pain, nausea or vomiting, extreme tiredness, dark-coloured urine, no appetite, itchy skin, skin and eyes appear yellowish (jaundice), swelling in the legs and ankles, pale, bloody or tar-coloured faeces, tendency to bruise easily
- if you experience symptoms of tardive dyskinesia (these include stiff, jerky movements of the tongue, mouth, face and body, that you are unable to control)
- if you are taking a psychostimulant (medicine used for (attention deficit hyperactivity disorder (ADHD) such as methylphenidate) as you may experience unwanted side effects when the dose of either medicine is changed
- if you experience symptoms of neuroleptic malignant syndrome (NMS) (these include high temperature, muscle stiffness, sweating, lowered level of consciousness, fast or irregular heartbeat)
- if you experience symptoms of prolactinaemia (abnormally high levels of the hormone prolactin in your blood) (these include overdevelopment of the breasts in men, difficulty in getting or maintaining an erection; in women breast discomfort or leakage of milk from the breasts, missed period or other problems with the menstrual cycle)

- if you suffer from high blood sugar levels and diabetes, as your blood sugar levels can worsen, or you are at risk of diabetes (e.g. obesity, family history of diabetes) or you experience thirst and hunger constantly, urinate more than normal and feel weak)
- if you had a stroke or suffer from any condition that might lead to a stroke, such as high blood pressure, heart disorder or blood vessel problems in the brain
- if you have heart problems or a family history of heart disease including heart failure, heart attacks, irregular heart rate, you are prone to become dehydrated, or if you experience low blood pressure (feel lightheaded or dizzy when standing up from a laying or sitting position). Your dose of ZOXADON ODT may need to be adjusted
- if you have a history of low levels of white blood cells (which may or may not have been caused by other medicines)
- if you are planning to have an eye operation as the coloured part of your eye may become floppy during surgery which may increase the risk of eye problems during and after cataract surgery
- if you suffer from epilepsy or seizures (fits), ZOXADON ODT may worsen the symptoms of these conditions
- if you are a man and you experience prolonged or a painful erection
- if you have problems controlling your body temperature or overheating in situations such as strenuous exercise, extreme heat, taking ZOXADON ODT with other medicines or when you are dehydrated
- if ZOXADON ODT is stopping you from vomiting
- ZOXADON ODT may cause you to gain weight. Significant weight gain may adversely affect your health. Your doctor should regularly measure your body weight
- if you or someone else in your family has a history of blood clots.

Elderly people with dementia:

In elderly patients with dementia, there is an increased risk of stroke. You should not take ZOXADON

ODT if you have dementia caused by stroke. During treatment with ZOXADON ODT 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 ODT 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:

- if your child/adolescent, whilst taking ZOXADON ODT, experiences any of the following: sleepiness, difficulty concentrating and learning, abnormal growth and development, or abnormal body movements
- before treatment is started your or your child's body weight may be measured and it may be regularly monitored during treatment.

A small and inconclusive study has reported an increase in height in children who took risperidone, but whether this is an effect of ZOXADON ODT or due to some other reason is not known.

Other medicines and ZOXADON ODT

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

It is especially important to tell your doctor if you are taking any of the following medicines which can affect the functioning of your heart:

- heart medicines that treats an abnormal heartbeat – quinidine, disopyramide, procainamide, propafenone, amiodarone, sotalol
- antidepression medicines – amitriptyline and maprotiline

- some antihistamine medicine (for allergy) e.g. terfenadine, astemizole
- malaria medicines – quinine and mefloquine
- other antipsychotic medicines
- medicines that cause lowering of potassium levels (e.g. hydrochlorothiazide, furosemide) and magnesium levels (e.g. furosemide).

It is also important to tell your doctor if you are taking any of the following medicines:

- opiates for pain (e.g. methadone), antihistamines for allergy (e.g. promethazine), benzodiazepines for anxiety (e.g. diazepam, alprazolam) in addition to ZOXADON ODT, can cause an increased feeling of drowsiness
- levodopa and other medicines in this class (to treat Parkinson's disease)
- blood pressure lowering medicines (e.g. enalapril, lisinopril, valsartan, telmisartan)
- paliperidone (to treat schizophrenia)
- fluoxetine and paroxetine (to treat depression)
- sertraline (to treat depression/panic disorders) and fluvoxamine (to treat obsessive compulsive disorder)
- verapamil (to treat high blood pressure, angina and heart conditions)
- cimetidine and ranitidine (blockers of the acidity of the stomach)
- itraconazole and ketoconazole (antifungal treatment)
- ritonavir (anti-HIV (human immunodeficiency virus) medicine)
- carbamazepine, phenytoin and phenobarbitone (to control types of epileptic seizures)
- rifampicin (tuberculosis (TB) treatment).

ZOXADON ODT may have an effect on the following medicines:

- furosemide (water tablets) together with ZOXADON ODT may have an increased risk of death in elderly patients with dementia (see Take special care with ZOXADON ODT)
- valproate (to control mania in patients suffering with bipolar disorder)

- topiramate (to treat seizures and prevent migraines in adults)
- phenothiazines (to calm you down)
- aripiprazole (to treat nervous conditions)
- amitriptyline, imipramine and venlafaxine (to treat depression)
- methylphenidate (treatment of behaviour and sleep disorders in adolescents and children)
- quetiapine (to treat schizophrenia and bipolar disorder)
- clozapine (to treat severe schizophrenia)
- lithium (to treat mania and episodes of manic depression)
- erythromycin (to treat or prevent many different types of infections caused by bacteria)
- donepezil or galantamine (to treat mild or moderate dementia caused by Alzheimer's disease)
- diazepam (to treat anxiety disorders)
- warfarin (to prevent blood clots)
- digoxin (to treat heart failure and heart rhythm disorders)
- some beta blockers, e.g. propranolol (to treat tremors, chest pain, high blood pressure and other heart conditions).

ZOXADON ODT with food, drink and alcohol

You can take ZOXADON ODT with or without food.

You should avoid drinking alcohol when taking ZOXADON ODT**.**

Pregnancy, breastfeeding and fertility

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

The safety of ZOXADON ODT in pregnant and breastfeeding women has not been established (see Do not take ZOXADON ODT).

Pregnancy

The following symptoms may occur in newborn babies, of mothers that have used ZOXADON ODT 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.

Breastfeeding

This medicine passes into breast milk. You should not take this medicine while you are breast-feeding your baby.

Fertility

ZOXADON ODT can raise your levels of a hormone called “prolactin”. This may impact fertility in both female and male patients

Driving and using machines

ZOXADON ODT may cause sleepiness, dizziness and a lack of concentration. Do not drive or operate any machinery before you know how ZOXADON ODT affects you.
It is not always possible to predict to what extent ZOXADON ODT 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 ODT affects them.

Important information about some of the ingredients of ZOXADON ODT:

ZOXADON ODT contain aspartame. Aspartame is a source of phenylalanine. It maybe harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the

body cannot remove it properly.

3. How to take ZOXADON ODT

Do not share medicines prescribed for you with any other person. Always use ZOXADON ODT exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will determine the correct dosage according to your condition.

Your doctor will tell you how long your treatment with ZOXADON ODT will last. If you have the impression that the effect of ZOXADON ODT is too strong or too weak, tell your doctor or pharmacist.

Instruction for taking ZOXADON ODT:

Only remove a tablet from the blister when it is time to take your medicine. Peel open a blister to expose the tablet.

Do not push the tablet through the foil as the tablet is fragile and may break.

Remove the tablet from the blister with clean dry hands and place the tablet on your tongue straight away.

The tablet will begin to disintegrate immediately. It can then be swallowed with or without water.

If taken with food, the mouth should be empty before placing the tablet on the tongue.

If you take more ZOXADON ODT 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:

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

If you forget to take ZOXADON ODT

- 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 ODT, ask your pharmacist for some hints.

If you stop taking ZOXADON ODT:

You should not stop taking ZOXADON ODT unless told to do so by your doctor. Your symptoms may return, and you may experience withdrawal symptoms such as sweating, nausea and vomiting. If your doctor decides to stop ZOXADON ODT, your dose may be decreased gradually over a few days.

4. Possible side effects

ZOXADON ODT can have side effects.

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

If any of the following happens, stop using ZOXADON ODT 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 ODT. 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:

- a blood clot in a vein (symptoms include swelling, pain and redness of the legs)
- blockage of an artery in the lungs (symptoms include sudden chest pains with difficulty breathing)
- you experience fever, muscle stiffness, sweating or a lowered level of consciousness (a disorder called neuroleptic malignant syndrome)
- you are a man and experience prolonged or painful erection. This is called priapism
- you experience repeated body movements including grimacing, sticking out the tongue or smacking the lips which you cannot control, stroke (general symptoms are sudden numbness, tingling, weakness or loss of movement in your face, arm, or leg, especially on only one side of your body), loss of consciousness, fainting, feeling extremely restless, difficulty in staying balanced, feeling of dizziness, difficulty with speaking, decreased sensitivity to stimuli, “pins and needles” feeling, coma due to diabetes (high blood sugar), stumbling/staggering or shaking of the head. These are signs of problems with your nervous system
- if the iris in your eye becomes floppy after cataract surgery
- rapid heart rate, abnormal heart rhythm, high blood pressure, shortness of breath, chest pain
- yellowing of the skin and whites of the eyes (jaundice) which are signs of liver problems.

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:

- infections of the urinary tract, upper respiratory tract, bronchitis, influenza and pneumonia

- raised levels of a hormone called prolactin found in a blood test, which may or may not cause the following symptoms, in men: breast swelling, difficulty in getting or maintaining erections, or other sexual dysfunction; in women: breast discomfort, leakage of milk from the breasts, missed menstrual periods or other problems with your cycle
- increase in weight, increased or decreased appetite
- sleeplessness, agitation, anxiety, lack of concentration, memory problems, mood changes, aggressive behaviour, feeling depressed
- headache, dizziness, sedation, increased dream activity, drowsiness, movement abnormalities such as tremor, slow movement, difficulty speaking, muscle stiffness, excessive saliva flow, slowness of movement, movements of the eyeballs into a fixed position, usually upwards, muscle quivering, restlessness and inability to sit still, involuntary muscle contractions that cause repetitive or twisting movements, muscle twitching
- blurred vision
- hypertension (high blood pressure)
- shortness of breath, rhinitis (blocked, runny, itchy nose, sneezing), cough, painful or sore throat, nosebleeds
- constipation, indigestion or upset stomach, nausea, dry mouth, diarrhoea, vomiting, stomach ache, stomach discomfort, toothache, decreased saliva flow
- red or itchy skin, skin rash
- back, joint or muscle pain, muscle cramps, pain in hands and/or feet
- bedwetting at night, frequent passing of urine or inability to pass urine, urinating more than normal amount
- tiredness, lack of energy, fever, chest pain, swollen hands and lower parts of the legs
- falling often.

Less frequent side effects:

- infections of the ear, respiratory tract (e.g. bronchitis, pneumonia and flu), bladder, eyes and

skin, tonsillitis, viral infections, fungal infection of the nails, acarodermatitis (inflammation of the skin of the hands or feet), sinusitis, on-going chronic infection of the middle ear

- decrease in the type of white blood cells that help to protect you against infection, decrease in platelets (blood cells that help you stop bleeding), anaemia (a decrease in red blood cells, symptoms include paleness, tired and feeling weak), increase in eosinophils (a type of white blood cell) in your blood
- excessive drinking of water, presence of glucose in the urine
- low and high blood sugar levels, higher than normal insulin levels in the blood, abnormal thirst, weight increase, anorexia
- hypomania (high energy levels, excessive enthusiasm, decrease in need to sleep), feeling confused or nervous, decrease in sex drive, nightmares, lack of emotion, listless
- eyes are light sensitive, dry eyes, increased tears from eyes, eye pain with visual disturbances, excess of blood in the white of the eyes (red eyes), increased pressure in the eyes (glaucoma), eye movement disorder, eye rolling, inflammation of the eyelid, eye infection (pink eye), eye swelling, eye discharge, loss of sight that cannot be corrected to a normal level with eyeglasses
- vertigo (feeling lightheaded or dizzy), tinnitus (ringing in the ears), ear pain
- low blood pressure (feeling lightheaded or dizzy) including when getting up from a sitting or lying position, skin flushing
- pneumonia aspiration (inflammation of the lungs caused by inhaling food), inflammation of the mucous membrane and sinuses, upper respiratory tract infections (nose, sinuses, back of throat, vocal cord), hyperventilation (very fast breathing), rattling sound in the lungs, hoarseness and change in pitch or quality of voice
- increased saliva in the mouth, unable to control your bowels, hard faeces, gastroenteritis/stomach flu (common symptoms are nausea, vomiting and stomach pains), difficulty swallowing, excess gas, swollen tongue/lips, inflammation of the lips
- increased liver transaminases in your blood, Increased GGT (a liver enzyme called gamma-

glutamyl transferase) in your blood, increased liver enzymes in your blood

- dry skin, increased skin pigmentation (darkening of the skin), increased sweating, eczema (inflamed, itchy, red, cracked and rough skin), oiliness of the skin, thickening of the skin, skin lesions, oversensitivity of skin to light, hives, itchy and severe skin rash, skin reaction, dandruff, skin discolouration, swelling of the deeper layers of the skin, caused by a build-up of fluid
- abnormal posture, joint stiffness, joint swelling, muscular weakness, neck pain, muscle ache
- signs of possible muscle tissue injury including muscle pain, weakness, vomiting, confusion and blood tests showing an increase in blood creatine phosphokinase
- need to urinate more often in the day, unable to urinate, pain when urinating, loss of bladder control
- sexual problems in men, including inability to get or maintain an erection, difficulty reaching orgasm or ejaculating, over development of breasts
- secretion of breast milk in men and women who are not breastfeeding
- sexual problems in women, including difficulty reaching orgasm, change in menstrual cycle, breast pain or enlargement, breast discomfort and vaginal discharge
- chills, increase in body temperature, abnormal manner of walking, thirst, chest discomfort, generally feeling unwell or discomfort, influenza-like illness
- you have problems controlling your body temperature or overheating
- drop in body temperature, coldness of the hands/feet, withdrawal effects if you stop taking ZOXADON ODT, including sweating, nausea, vomiting or a return of the condition which ZOXADON ODT is treating (see Effects when treatment with ZOXADON ODT is stopped)
- blood tests showing abnormal kidney function, liver function, muscle injury, blood sugar, red and white cell levels, decreased body temperature
- pain when procedures are performed, e.g. wound care.

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

- blood test results showing dangerously low levels of white blood cells (agranulocytosis)
- diabetes or worsening of diabetes (with symptoms such as excessive thirst, increased urination, constant hunger), blood cholesterol increase, low blood sugar levels
- mania (periods of great excitement or euphoria, delusions, and over-activity)
- bad taste in the mouth, a state of immobility and stupor, sleep-related eating disorder
- sleep disorder in which breathing involuntarily stops and starts (this continues repeatedly)
- blockage of the small or large intestine, inflammation of the pancreas (common symptoms include pain in the upper abdomen/belly, nausea and vomiting),
- hair loss on the body and head
- the following symptoms may occur in newborn babies if the mother was taking ZOXADON ODT in the last three months of pregnancy: shaking, muscle stiffness, and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding
- hardened lump on the skin or under the skin, hypothermia (an emergency situation that occurs when your body loses heat faster than it can produce heat).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

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

5. How to store ZOXADON ODT

Store all medicines out of reach of children.

Store below 30 ˚C.

Protect from moisture.

Keep blisters in the carton until required for use.

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 ODT contains:

The active ingredient is risperidone.

ZOXADON ODT 0,5 mg contains risperidone 0,5 mg.

ZOXADON ODT 1 mg contains risperidone 1 mg.

ZOXADON ODT 2 mg contains risperidone 2 mg.

The other ingredients are:

Aspartame, basic butylated methacrylate copolymer, calcium silicate, crospovidone, flavour peppermint, flavour spearmint, hydroxypropyl cellulose, iron oxide red, magnesium stearate, mannitol, microcrystalline cellulose and povidone.

ZOXADON ODT contains sweetener (aspartame) in the following quantities: 0,4 mg, 0,8 mg and 1,6 mg per 0,5 mg, 1 mg and 2 mg tablet, respectively.

ZOXADON ODT contains sugar (mannitol 27,8 mg, 55,6 mg and 111,2 mg per 0,5 mg, 1 mg and 2 mg tablet, respectively).

What ZOXADON ODT looks like and contents of the pack

ZOXADON ODT 0,5 mg: Round (diameter = 5 mm), slightly biconvex, pink marbled orodispersible tablet.

ZOXADON ODT 1 mg: Round (diameter = 6 mm), slightly biconvex, pink marbled orodispersible tablet.

ZOXADON ODT 2 mg: Round (diameter = 8 mm), slightly biconvex, pink marbled orodispersible tablet.

ZOXADON ODT is packed in blisters consisting of cold formed OPA/Al/PVC film and PET/Al peel off foil in packs of 30's in an outer carton.

Holder of Certificate of Registration

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