ZOXADON ODT

SCHEDULING STATUS S5

1. NAME OF THE MEDICINE
ZOXADON ODT 0,5 mg orodispersible tablets
ZOXADON ODT 1 mg orodispersible tablets
ZOXADON ODT 2 mg orodispersible tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Active ingredient:
ZOXADON ODT 0,5 mg: Each orodispersible tablet contains risperidone 0,5 mg
ZOXADON ODT 1 mg: Each orodispersible tablet contains risperidone 1 mg
ZOXADON ODT 2 mg: Each orodispersible tablet contains risperidone 2 mg

Excipients with known effect:
ZOXADON ODT contains sweetener (aspartame) in the following quantities: 0,4 mg, 0,8 mg, 1,6 mg per 0,5 mg, 1 mg, 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).
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Orodispersible tablets.
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.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
ZOXADON ODT tablets are indicated for the treatment of:
- acute and chronic schizophrenic psychoses and related psychosis in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility and suspicion) and/or the negative symptoms (such as blunted affect, emotional and social withdrawal, and poverty of speech) are prominent.
  ZOXADON ODT tablets also alleviate affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. In patients who have shown an initial treatment response, ZOXADON ODT tablets are also effective in maintaining the clinical improvement
- conduct and other disruptive behaviour disorders in children (aged 5 - 12 years), with sub-average intellectual functioning or mental retardation in whom destructive behaviours (e.g. aggression, impulsivity and self-injurious behaviours) are prominent
  The weight of the child should be 50 kg and above 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.

4.2 Posology and method of administration
Posology
Schizophrenia:
Switching from other antipsychotics to ZOXADON ODT:
When medically appropriate, gradual discontinuation of the previous treatment, while ZOXADON ODT therapy is initiated, is recommended. Also, if medically appropriate, when switching patients from depot antipsychotics, initiate ZOXADON ODT therapy in place of the next scheduled injection. The need for continuing existing anti-Parkinson medicines should be re-evaluated periodically.

Adults
ZOXADON ODT may be given once or twice daily. Patients should start with ZOXADON ODT 2 mg/day. The dosage may be increased on the second day to 4 mg/day. From then on, the dosage can be maintained unchanged, or further individualised, if needed. Most patients will benefit from daily doses of between 4 mg/day and 8 mg/day. Doses above 6 mg/day (when administered twice daily) were associated with more extrapyramidal symptoms and other adverse effects, and are not recommended. In some patients, particularly with first episode acute psychosis, a slower titration phase and a lower starting and maintenance dose may be appropriate. Doses above 10 mg/day have not been shown to be superior in efficacy to lower doses and may cause an increased incidence of side effects such as extrapyramidal symptoms. Dosages above 10 mg/day should only be considered if the benefits outweigh the risk. The maximum total daily dose is 16 mg/day.
A benzodiazepine may be added to ZOXADON ODT if additional sedation is required.

Special populations
Elderly
It is recommended to half both the starting dose and the subsequent dose increments in elderly patients.
A starting dose of 0,5 mg twice daily is recommended. This dosage can be individually adjusted with 0,5 mg twice daily increments to 1 - 2 mg twice daily.

Paediatric population
Children
Not for children under 15 years as efficacy and safety in children under the age of 15 years have not been demonstrated in schizophrenia.

Mania in bipolar disorders:
Adults
ZOXADON ODT should be administered on a once daily schedule, starting with 2 or 3 mg. Dosage adjustments, if indicated, should occur at intervals of not less than 24 hours and in dosage increments of 1 mg per day. Efficacy was demonstrated in flexible doses over a range of 1 - 6 mg per day.
The continued use of ZOXADON ODT must be evaluated and justified on an ongoing basis.

Special populations
Paediatric
Experience is lacking in bipolar mania in children and adolescents less than 18 years of age.

Conduct and other disruptive behaviour disorders in children 5 - 12 years of age (50 kg and over)
This formulation is not suitable for the treatment of behavioural disturbances in children under 50 kg.
A starting dose of 0,01 mg/kg once daily is recommended. This dosage can be individually adjusted by increments of 0,01 mg/kg once daily, not more frequently than every other day, if needed. The recommended maintenance dose is 0,02 - 0,04 mg/kg once daily. The mean dose is 0,03 mg/kg once daily.
The continued use of ZOXADON ODT must be evaluated and justified on an ongoing basis. Experience is lacking in children aged less than 5 years (see section 4.3).

Renal and hepatic impairment
Patients with renal impairment have less ability to eliminate the active antipsychotic fraction than normal adults. Patients with impaired hepatic function have increases in plasma concentration of the free fraction of risperidone. Irrespective of the indication, starting and consecutive dosing should be halved, and dose titration should be slower for patients with renal or hepatic impairment.
ZOXADON ODT should be used with caution in these groups of patients.

Method of administration
ZOXADON ODT can be taken before or after food (see section 5.1).
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.

Missed dose:
Medical practitioners should advise patients who forget to take ZOXADON ODT to take a dose as soon as possible and then continue with the normal dose. Patients should not take a double dose to compensate for the missed dose.

4.3 Contraindications
- hypersensitivity to risperidone or to any of the ingredients of ZOXADON ODT
- conduct and other disruptive behaviour disorders in children: ZOXADON ODT is contraindicated in children under 5 years of age as efficacy and safety in these children have not been demonstrated
- safety of ZOXADON ODT tablets in pregnancy or lactating women has not been established (see section 4.6)
- Parkinson's disease and Lewy body dementia (see section 4.4).

4.4 Special warnings and precautions for use
This formulation is not suitable for the treatment of behavioural disturbances in children weighing less than 50 kg, and adults with dementia.

Dementia associated with Parkinson's disease and senile dementia
Patients with Parkinson's disease or dementia with Lewy bodies (DLB) may be at risk of neuroleptic malignant syndrome (NMS) as well as an increased sensitivity to antipsychotic medicines such as ZOXADON ODT. Manifestations of this increased sensitivity can include confusion, obtundation, and postural instability with frequent falls, in addition to extrapyramidal symptoms.
In clinical trials, elderly ZOXADON ODT treated patients had a higher mortality than placebo treated elderly patients. Caution should be used when prescribing ZOXADON ODT to patients with Parkinson's disease since it might cause a deterioration of the disease (see section 4.3).

Increased mortality in elderly people with dementia
Elderly patients with dementia, when treated with atypical antipsychotics such as ZOXADON ODT, have an increased mortality.

Concomitant use with furosemide
There is a higher mortality in elderly patients with dementia treated with furosemide and risperidone, when compared to patients treated with ZOXADON ODT alone. No pathophysiological mechanism has been identified to explain this finding, and no consistent pattern for cause of death observed. Caution is advised in these patients. Dehydration is an overall risk for mortality and should therefore be carefully avoided in elderly patients with dementia. Concomitant use of ZOXADON ODT with other diuretics (mainly thiazide diuretics used in low dose) is not associated with similar findings.

Renal and hepatic impairment
Patients with renal impairment have less ability to eliminate the active antipsychotic fraction of ZOXADON ODT than adults with normal renal function. Patients with impaired hepatic function have increases in plasma concentration of the free fraction of risperidone (see section 4.2).

Tardive dyskinesia
Tardive dyskinesia (TD), a syndrome consisting of potentially irreversible, involuntary dyskinetic movements predominantly of the face and tongue, may develop in patients treated with ZOXADON ODT. Although this syndrome of TD appears to be most prevalent in the elderly, especially elderly females, it is impossible to predict at the onset of treatment which patients are likely to develop TD.
It has been suggested that the occurrence of Parkinsonian side effects is a predictor for the development of TD. The risk of developing TD and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of ZOXADON ODT administered to the patient increases. However, the syndrome can develop, although less commonly, after relatively brief periods of treatment at low doses.
There is no known treatment for an established case of TD. The syndrome may remit partially or completely if ZOXADON ODT is withdrawn.
ZOXADON ODT treatment itself, however, may suppress the signs and symptoms of TD, thereby masking the underlying process. The effect of symptom suppression upon the long-term course of TD is unknown. In view of these considerations, ZOXADON ODT should be prescribed in a manner that is most likely to minimise the risk of TD. ZOXADON ODT should be reserved for patients who appear to be obtaining substantial benefit from the medicine. In such patients the smallest dose and the shortest duration of treatment should be sought.
The benefit for continued treatment should be reassessed periodically. If signs and symptoms of TD appear in a patient, ZOXADON ODT discontinuation should be considered. However, some patients may require treatment despite the presence of this syndrome.

Extrapyramidal symptoms and psychostimulants - Caution is warranted in patients receiving both psychostimulants (e.g. methylphenidate) and risperidone concomitantly, as extrapyramidal symptoms could emerge when adjusting one or both medications (see section 4.5).

Neuroleptic malignant syndrome
Neuroleptic malignant syndrome (NMS) is a potentially fatal symptom complex that has been reported in association with the use of ZOXADON ODT. Clinical manifestations of NMS are hyperthermia, muscle rigidity, altered mental status (including catatonic signs) and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, cardiac dysrhythmias and diaphoresis). Additional signs may include elevated creatine phosphokinase (CPK) levels, myoglobinuria (rhabdomyolysis), and acute renal failure.
In arriving at a diagnosis, it is important to identify cases where the clinical presentation includes both serious medical illnesses (e.g. pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, medicine fever and primary central nervous system pathology.

The management of NMS should include:
1. immediate discontinuation of all antipsychotic medicines and other medicines not essential to concurrent therapy;
2. intensive symptomatic treatment and medical monitoring; and
3. treatment of any concomitant serious medical problems for which specific treatments are available.

There is no general agreement about specific pharmacological treatment regimens for uncomplicated NMS.
If a patient requires ZOXADON ODT treatment after recovery from NMS, the potential reintroduction of the medicine should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported.

Hyperprolactinaemia
Hyperprolactinaemia is a common side effect of treatment with ZOXADON ODT. A dose-dependent increase in plasma prolactin concentration may occur. Evaluation of the prolactin plasma level is recommended in patients with evidence of possible prolactin-related side effects (e.g. gynaecomastia, menstrual disorders, anovulation, fertility disorder, decreased libido, erectile dysfunction and galactorrhoea).
Cell growth in human breast tumours may be stimulated by prolactin. Although no clear association with the administration of antipsychotics, such as ZOXADON ODT, has so far been demonstrated, caution is recommended in patients with relevant medical history. ZOXADON ODT should be used with caution in patients with pre-existing hyperprolactinaemia and in patients with possible prolactin-dependent tumours.
Premenopausal women who develop secondary amenorrhoea of greater than six months duration should receive appropriate preventative therapy to avoid hypo-oestrogenic bone loss.

Hyperglycaemia and diabetes mellitus
Hyperglycaemia and exacerbation of pre-existing diabetes mellitus have been reported on ZOXADON ODT treatment. Hyperglycaemia, in some cases extreme and associated with ketoacidosis and hyperosmolar coma or death, has been reported in patients treated with ZOXADON ODT. Patients with an established diagnosis of diabetes mellitus who are started on ZOXADON ODT should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g. obesity, family history of diabetes) who are starting treatment with ZOXADON ODT should be monitored for symptoms of hyperglycaemia including polydipsia, polyuria, polyphagia and weakness. Patients who develop symptoms of hyperglycaemia during treatment with ZOXADON ODT should undergo fasting blood glucose testing. In some cases, hyperglycaemia has resolved when ZOXADON ODT was discontinued. However, some patients required continuation of antidiabetic treatment despite discontinuation of ZOXADON ODT.

Cerebrovascular adverse events
Cerebrovascular adverse events (CVAEs), including cerebrovascular accidents and transient ischaemic attacks, have been reported during treatment with ZOXADON ODT. There is a higher incidence of cerebrovascular adverse events, including cerebrovascular accidents, transient ischaemic attacks and fatalities, in elderly patients with dementia treated with ZOXADON ODT.
The risk of CVAEs was significantly higher in patients with mixed or vascular type of dementia when compared to Alzheimer's dementia. Therefore, patients with types of dementias other than Alzheimer's should not be treated with ZOXADON ODT.
Patients/caregivers should be cautioned to immediately report signs and symptoms of potential CVAEs such as sudden weakness or numbness in the face, arms or legs, and speech or vision problems. All treatment options should be considered without delay, including discontinuation of ZOXADON ODT.
ZOXADON ODT should only be used short term for persistent aggression in patients with moderate to severe Alzheimer's dementia to supplement non-pharmacological approaches which have had limited or no efficacy and when there is potential risk of harm to self or others.
Caution is advised in all patients with risk factors for stroke, and regular assessment for the need for ZOXADON ODT treatment is recommended.

Orthostatic hypotension
Due to the alpha-blocking activity of ZOXADON ODT, (orthostatic) hypotension can occur, especially during the initial dose-titration period. ZOXADON ODT should be used with caution in patients with known cardiovascular disease (e.g. heart failure, myocardial infarction, conduction abnormalities, dehydration, hypovolaemia or cerebrovascular disease), and the dosage should be gradually titrated, as recommended. A dose reduction should be considered if hypotension occurs.

Leukopaenia, neutropenia and agranulocytosis
Events of leukopaenia, neutropenia and agranulocytosis have been reported with risperidone, with agranulocytosis reported during post-marketing surveillance.
Patients with a history of a clinically significant low white blood cell count (WBC) or a drug-induced leukopaenia/neutropenia should be monitored during the first few months of therapy and discontinuation of ZOXADON ODT should be considered at the first sign of a clinically significant decline in WBC in the absence of other causative factors.
Patients with clinically significant neutropenia should be carefully monitored for fever or other symptoms or signs of infection and treated promptly if such symptoms or signs occur.
Patients with severe neutropenia (absolute neutropenia count $< 1 \times 10^9$/L) should discontinue ZOXADON ODT and have their WBC followed until recovery.

QT prolongation
QT prolongation has been reported with the use of risperidone, as in ZOXADON ODT.
Caution should be exercised when ZOXADON ODT is prescribed in patients with known cardiovascular disease, family history of QT prolongation, bradycardia or electrolyte disturbances (hypokalaemia, hypomagnesaemia), as it may increase the risk of dysrhythmogenic effects, and in concomitant use with medicines known to prolong the QT interval.

Intraoperative floppy iris syndrome
Cases of intraoperative floppy iris syndrome (IFIS) during cataract surgery have been reported in patients taking risperidone, as in ZOXADON ODT. IFIS may increase the risk of eye complications during and after cataract surgery. Complications of IFIS during cataract surgery include iris trauma: posterior capsule rupture and vitreous loss. Post-operative complications include increased intraocular pressure and cystoid macular oedema. It is therefore recommended to verify pre-surgery data gathering on patient history and the previous or current use of ZOXADON ODT.

Pituitary adenomas
Benign pituitary adenomas have been reported during post-marketing surveillance. No causal association could be detected.

Seizures
Seizures have been reported after treatment with ZOXADON ODT. Caution is recommended when treating patients with epilepsy or other conditions that potentially lower the seizure threshold.

Priapism
Priapism may occur with ZOXADON ODT treatment due to its alpha-adrenergic blocking effects and has been reported during post-marketing surveillance (see section 4.8).

Body temperature regulation
ZOXADON ODT may disrupt the body's ability to reduce core body temperature. ZOXADON ODT should be used with caution in patients who experience conditions that contribute to an increase in core body temperature, e.g. strenuous exercise, exposure to extreme heat, concomitant use with anticholinergic medicines, or being subject to dehydration.

Antiemetic effect
ZOXADON ODT may have an antiemetic effect which could mask the signs and symptoms of overdosage with certain medicines or conditions such as intestinal obstruction, Reye's syndrome and brain tumour.

Weight gain
Weight gain has been reported with ZOXADON ODT use. Weight should be monitored regularly.

Venous thromboembolism (VTE)
Since patients treated with antipsychotics, such as ZOXADON ODT, often present with acquired risk factors for VTE, all possible risk factors for VTE should be identified before and during treatment with ZOXADON ODT, and preventative measures taken.

Stopping ZOXADON ODT treatment:
Gradual withdrawal of ZOXADON ODT is recommended because of the risk of withdrawal symptoms, including sweating, nausea, vomiting and rebound psychosis, with abrupt cessation of treatment.

Information on excipients of ZOXADON ODT:
Aspartame is hydrolysed in the gastrointestinal tract when orally ingested. One of the major hydrolysis products is phenylalanine, which may be harmful to patients with phenylketonuria. Neither non-clinical nor clinical data are available to assess aspartame use in infants below 12 weeks of age.

Paediatric population
Before ZOXADON ODT is prescribed to a child or adolescent with a conduct disorder, they should be carefully assessed for physical and social causes of the aggressive behaviour, such as pain or inappropriate environmental demands. The sedative effect should be carefully monitored in this population due to the possible impact on learning ability. A change in the time of administration of ZOXADON ODT could improve the impact of the sedation on attention faculties of children and adolescents.
ZOXADON ODT is associated with increases in body weight and body mass index, therefore baseline weight measurement prior to treatment, and regular weight monitoring, is recommended.
Because of the potential effects of prolonged hyperprolactinaemia on growth and sexual maturation in children and adolescents, regular clinical evaluation of endocrinological status should be considered, including measurements of height, weight, sexual maturation, monitoring of menstrual functioning, and other potential prolactin-related effects. Regular examination for extrapyramidal symptoms and other movement disorders should also be conducted during treatment with ZOXADON ODT.

4.5 Interaction with other medicines and other forms of interaction
Pharmacodynamic-related interactions
Medicines known to prolong the QT interval:
Caution is advised when prescribing ZOXADON ODT with medicines known to prolong the QT interval, such as antidysrhythmics (e.g. quinidine, disopyramide, procainamide, propafenone, amiodarone, sotalol), tricyclic antidepressants (i.e. amitriptyline), tetracyclic antidepressants (i.e. maprotiline), some antihistamines, other antipsychotics, some antimalarials (i.e. quinine and mefloquine) and with medicines causing electrolyte imbalance (hypokalaemia, hypomagnesaemia), bradycardia, or those which inhibit the hepatic metabolism of ZOXADON ODT. This list is indicative and not exhaustive.

Centrally acting medicines and alcohol:
Given the primary central nervous system (CNS) depressive effects of ZOXADON ODT, it should be used with caution in combination with alcohol and other centrally acting medicines, including opiates, antihistamines and benzodiazepines due to increased risk of sedation.

Levodopa and dopamine agonists:
ZOXADON ODT may antagonise the effect of levodopa and other dopamine agonists. If this combination is deemed necessary, particularly in end-stage Parkinson's disease, the lowest effective dose of each treatment should be prescribed.

Medicines with hypotensive effect:
Clinically significant hypotension has been observed with concomitant use of ZOXADON ODT and antihypertensive treatment.

Psychostimulants:
The combined use of psychostimulants (e.g. methylphenidate) with ZOXADON ODT can lead to extrapyramidal symptoms upon change of either or both treatments (see section 4.4).

Paliperidone:
Concomitant use of ZOXADON ODT with paliperidone is not recommended as paliperidone is the active metabolite of risperidone, and the combination of the two may lead to additive antipsychotic fraction exposure.

Pharmacokinetic-related interactions
Food does not affect the absorption of risperidone.

Risperidone, as in ZOXADON ODT, is mainly metabolised through cytochrome P450 2D6 (CYP2D6), and to a lesser extent through CYP3A4. Both risperidone and its active metabolite 9-hydroxyrisperidone are substrates of P-glycoprotein (P-gp) activity. Substances that modify CYP2D6 activity, or substances strongly inhibiting or inducing CYP3A4 and P-gp, may influence the pharmacokinetics of risperidone active antipsychotic fraction.

Strong CYP2D6 inhibitors:
Co-administration of risperidone with a strong CYP2D6 inhibitor may increase the plasma concentrations of ZOXADON ODT, but less so of the active antipsychotic fraction. Higher doses of a strong CYP2D6 inhibitor may elevate concentrations of the risperidone active antipsychotic fraction (e.g. paroxetine, see below). It is expected that other CYP2D6 inhibitors, such as quinidine, may affect the plasma concentrations of ZOXADON ODT in a similar way. When concomitant paroxetine, quinidine, or another strong CYP2D6 inhibitor, especially at higher doses, is initiated or discontinued, the medical practitioner should re-evaluate the dosing of ZOXADON ODT.

CYP3A4 and/or P-gp inhibitors:
Co-administration of risperidone with a strong CYP3A4 and/or P-gp inhibitor may substantially elevate plasma concentrations of the ZOXADON ODT active antipsychotic fraction. When concomitant itraconazole or another strong CYP3A4 and/or P-gp inhibitor is initiated or discontinued, the medical practitioner should re-evaluate the dosing of ZOXADON ODT.

CYP3A4 and/or P-gp inducers:
Co-administration of risperidone with a strong CYP3A4 and/or P-gp inducer may decrease the plasma concentrations of the ZOXADON ODT active antipsychotic fraction.
When concomitant carbamazepine or another strong CYP3A4 and/or P-gp inducer is initiated or discontinued, the medical practitioner should re-evaluate the dosing of ZOXADON ODT.
CYP3A4 inducers exert their effect in a time-dependent manner and may take at least 2 weeks to reach maximal effect after introduction. Conversely, on discontinuation, CYP3A4 induction may take at least 2 weeks to decline.

Highly protein-bound drugs:
When ZOXADON ODT is taken together with other highly protein-bound medicines (e.g. diazepam, warfarin, digoxin, imipramine and propranolol), there is no clinically relevant displacement of either medicine from the plasma proteins.
When using concomitant medication, the corresponding label should be consulted for information on the route of metabolism and the possible need to adjust dosage.

Effects of other medicines on the pharmacokinetics of ZOXADON ODT:
Antiepileptics:
Carbamazepine, a strong CYP3A4 inducer and P-gp inducer decreases the plasma levels of the active antipsychotic fraction of risperidone by about 50 %. Similar effects may be observed with other hepatic enzyme inducers e.g. phenytoin and phenobarbitone. On discontinuation of carbamazepine or other hepatic enzyme inducers, the dosage of ZOXADON ODT should be re-evaluated and, if necessary, decreased.
Valproate: valproate T_{max} increases from 1,3 hours to 2,0 hours showing no clinically relevant effect.
Topiramate: modest decrease in risperidone bioavailability, but not that of the active antipsychotic fraction. Therefore, this interaction is unlikely to be of clinical significance.

Antipsychotics:
Phenothiazines may increase the plasma concentration of risperidone but not that of the antipsychotic fraction.

Selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants:
Fluoxetine and paroxetine, strong CYP2D6 inhibitors, increase the plasma concentration of risperidone but less so of the antipsychotic fraction. Doses of paroxetine higher than 20 mg/day may elevate the concentrations of the risperidone active antipsychotic fraction.
Fluoxetine kinetics were not changed in combination with ZOXADON ODT. When concomitant fluoxetine or paroxetine is initiated or discontinued, the dosing of ZOXADON ODT should be re-evaluated.
Tricyclic antidepressants may increase the plasma concentrations of risperidone but not those of the active antipsychotic fraction. Amitriptyline does not affect the pharmacokinetics of ZOXADON ODT or the active antipsychotic fraction.
Sertraline, a weak inhibitor of CYP2D6, and fluvoxamine, a weak inhibitor of CYP3A4, at dosages up to 100 mg/day, are not associated with clinically significant changes in concentrations of the risperidone active antipsychotic fraction. However, doses higher than 100 mg/day of sertraline or fluvoxamine may elevate concentrations of the risperidone active antipsychotic fraction.
Venlafaxine: risperidone area under the curve (AUC) increased and risperidone clearance decreased, but there is no effect on 9-hydroxyrisperidone and the active moiety.
Quetiapine: no significant interaction.
Clozapine: no significant interaction.

Antibacterials:
Erythromycin, a moderate CYP3A4 inhibitor and P-gp inhibitor, does not change the pharmacokinetics of risperidone and the antipsychotic fraction.
Rifampicin, a strong CYP3A4 inducer and a P-gp inducer, decreases the plasma concentrations of the active antipsychotic fraction.

Antifungals:
Itraconazole, a strong CYP3A4 inhibitor and a P-gp inhibitor, at a dosage of 200 mg/day increases the plasma concentrations of the active antipsychotic fraction by about 70 %, at risperidone doses of 2 - 8 mg/day.
Ketoconazole, a strong CYP3A4 inhibitor and a P-gp inhibitor, at a dosage of 200 mg/day increases the plasma concentrations of risperidone and decreases plasma concentrations of 9-hydroxyrisperidone.

Antivirals:
Protease inhibitors: No formal study data are available, however, since ritonavir is a strong CYP3A4 inhibitor and a weak CYP2D6 inhibitor, ritonavir and ritonavir-boosted protease inhibitors potentially raise concentrations of the risperidone active antipsychotic fraction.

Anticholinesterases:
There were non-significant effects on risperidone kinetics or that of the active antipsychotic fraction in combination with donepezil or galantamine, both CYP2D6 and CYP3A4 substrates.

Beta blockers:
Some beta blockers may increase the plasma concentrations of risperidone but not those of the active antipsychotic fraction.

Calcium channel blockers:
Verapamil, a moderate inhibitor of CYP3A4 and an inhibitor of P-gp, increases the plasma concentration of risperidone and the antipsychotic fraction.

Gastrointestinal medicines:
Cimetidine and ranitidine, both weak inhibitors of CYP2D6 and CYP3A4, increase the bioavailability of risperidone, but only marginally that of the active antipsychotic fraction.

Effect of ZOXADON ODT on the pharmacokinetics of other medicines:
Diuretics:
Furosemide: increases mortality in elderly patients with dementia (see section 4.4).

Antiepileptics:
ZOXADON ODT shows no clinically relevant effect on the pharmacokinetics of valproate or topiramate.

Antipsychotics:
Aripiprazole, a CYP2D6 and CYP3A4 substrate: ZOXADON ODT shows no effect on the pharmacokinetics of aripiprazole or its active metabolite, dehydroaripiprazole.

Lithium: C_{max} and AUC of lithium are non-significantly increased, but T_{max} of lithium is increased from 2,4 hours to 3,0 hours. ZOXADON ODT shows no clinically relevant effect on the pharmacokinetics of lithium.

Galantamine and donepezil, do not show a clinically relevant effect on the pharmacokinetics of risperidone and the active antipsychotic fraction.

Paediatric population
Interaction studies have only been performed in adults. The relevance of the results from these studies in paediatric patients is unknown.
The combined use of psychostimulants (e.g. methylphenidate) with ZOXADON ODT in children and adolescents did not alter the pharmacokinetics and efficacy of ZOXADON ODT.

4.6 Fertility, pregnancy and lactation
The safety of ZOXADON ODT in pregnancy and lactating women has not been established (see section 4.3).

Pregnancy
Reversible extrapyramidal symptoms, including hypertonia, hypotonia, jitteriness, tremor, muscle rigidity, twitching and convulsions, feeding disorder and withdrawal symptoms have been observed in neonates following use of risperidone, as in ZOXADON ODT, during the last trimester of pregnancy.

Breastfeeding
Risperidone and 9-hydroxyrisperidone are excreted in human breast milk. Therefore, women receiving ZOXADON ODT should not breastfeed their infants.

Fertility
Risperidone elevates prolactin levels. Hyperprolactinaemia may suppress hypothalamic gonadotropin-releasing hormone (GnRH), resulting in reduced pituitary gonadotropin secretion. This, in turn, may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients. There were no relevant effects observed in non-clinical studies.

4.7 Effects on ability to drive and use machines
ZOXADON ODT can have minor or moderate influence on the ability to drive and use machines due to potential nervous system and visual effects (see section 4.8).
ZOXADON ODT may impair mental alertness. Patients should therefore be advised not to drive or operate machinery until their individual susceptibility is known.

4.8 Undesirable effects
a. Summary of the safety profile
The most frequently reported adverse drug reactions (ADRs) defined as very frequent (incidence ≥ 10%) are: Parkinsonism, sedation/somnolence, headache and insomnia.
The ADRs that appeared to be dose-related included parkinsonism and akathisia.

b. Tabulated list of adverse reactions

System Organ Class	Frequency	Side effects
Infections and Infestations	*Frequent*	Urinary tract infection, pneumonia, influenza, bronchitis, upper respiratory tract infection
	Less frequent	Respiratory tract infection, cystitis, eye infection, ear infection, otitis media, tonsillitis, onychomycosis, cellulitis localised infection, viral infection, acarodermatitis, sinusitis, chronic otitis media
Blood and lymphatic system disorders	*Less frequent*	A decrease in neutrophil and/or thrombocyte count, leukopaenia, neutropenia, granulocytopenia, anaemia, decreased haematocrit count, increased eosinophil count
	Frequency unknown	Agranulocytosis, thrombocytopaenia
Immune system disorders	*Less frequent*	Hypersensitivity, drug hypersensitivity
	Frequency unknown	Angioedema*, anaphylactic reaction*
Endocrine disorders	*Frequent*	Increased plasma prolactin levels and associated manifestations
	Less frequent	Water intoxication, either due to polydipsia or the syndrome of inappropriate secretion of the antidiuretic hormone (SIADH), glucose urine present
	Frequency unknown	Body temperature dysregulation, inappropriate antidiuretic hormone secretion
Metabolism and nutrition disorders	*Frequent*	Weight increase, increase/decrease appetite
	Less frequent	Hyperglycaemia, polydipsia, weight decrease, anorexia, hyperinsulinaemia
	Frequency unknown	Diabetes mellitus*, diabetic ketoacidosis*, hypoglycaemia*, blood cholesterol increase*, blood triglycerides increase*, water intoxication
Psychiatric disorders	*Frequent*	Insomnia, agitation, anxiety, sleep disorder, impaired concentration, memory problems, mood or mental changes including aggressive behaviour, depression
	Less frequent	Hypomania, confusional state, libido decrease, listless, nervousness, nightmare,blunted affect, anorgasmia
	Frequency unknown	Mania*
Nervous system disorders	*Frequent*	Parkinsonism, headache, extrapyramidal disorder, dizziness, sedation, increased dream activity, somnolence, tremor, rigidity, hypersalivation, bradykinesia, oculogyric crisis, akathisia (hyperkinesia) and acute dystonia, hypokinesia, lethargy, dyskinesia
	Less frequent	Tardive dyskinesia, neuroleptic malignant syndrome, cerebrovascular incidents, cerebral ischaemia, unresponsive to stimuli, loss of consciousness, decreased level of consciousness, convulsion, syncope, psychomotor hyperactivity, balance disorder, abnormal co-ordination, postural dizziness, disturbance in attention, dysarthria, hypoaesthesia, paraesthesia, cerebrovascular disorder, diabetic coma, head titubation, hypersomnia, speech disorder, movement disorder
	Frequency unknown	Dysgeusia*, catatonia*, somnambulism*, sleep-related eating disorder*
Eye disorders	*Frequent*	Blurred vision
	Less frequent	Photophobia, dry eyes, increased lacrimation, ocular hyperaemia, glaucoma, eye movement disorder, eye rolling, eyelid margin crusting, conjunctivitis, eye discharge, eye swelling, reduced visual acuity
	Frequency unknown	Floppy iris syndrome (intraoperative)*
Ear and labyrinth disorders	*Less frequent*	Vertigo, tinnitus, ear pain
Cardiac disorders	*Frequent*	Tachycardia
	Less frequent	Chest pain, palpitations, aterioventricular block, QT prolongation, abnormal electrocardiogram, conduction disorders, sinus dysrhythmia, bradycardia
	Frequency unknown	Atrial fibrillation*, electrocardiogram (ECG) QT prolonged
Vascular disorders	*Frequent*	Hypertension
	Less frequent	Hypotension, orthostatic hypotension, flushing, pulmonary embolism, venous thrombosis
Respiratory, thoracic and mediastinal disorders	*Frequent*	Dyspnoea, rhinitis, cough, pharyngolaryngeal pain, pharyngitis, epistaxis, nasal congestion
	Less frequent	Pneumonia aspiration, pulmonary congestion, respiratory tract congestion, rales, wheezing, dysphonia, sinusitis, upper respiratory tract infection, respiratory disorder, hyperventilation, dysphonia
	Frequency unknown	Sleep apnoea syndrome*
Gastrointestinal disorders	*Frequent*	Constipation, dyspepsia, nausea, decreased salivation, diarrhoea, vomiting, abdominal pain, abdominal discomfort, dry mouth,toothache
	Less frequent	Hypersalivation, faecal incontinence, faecaloma, gastroenteritis, dysphagia, flatulence, swollen tongue, swollen lips, cheilitis
	Frequency unknown	Ileus*, intestinal obstruction*, pancreatitis*
Hepatobiliary disorders	*Less frequent*	Increased transaminases, gamma-glutamyl transferase (GGT) and hepatic enzymes
	Frequency unknown	Jaundice*
Skin and subcutaneous tissue disorders	*Frequent*	Skin rash, itching, erythema
	Less frequent	Dry skin, increased pigmentation, increased sweating, photosensitivity, seborrhoea, urticaria, pruritus, eczema, acne, hyperkeratosis, skin disorder, skin lesions, drug eruption, dandruff, skin discolouration, angioedema
	Frequency unknown	Alopecia*
Musculoskeletal, connective tissue and bone disorders	*Frequent*	Back pain, arthralgia, muscle spasms, musculoskeletal pain, pain in extremities
	Less frequent	Increase in blood creatine phosphokinase, abnormal posture, joint stiffness, joint swelling, muscular weakness, myalgia, neck pain, rhabdomyolysis
Renal and urinary disorders	*Frequent*	Enuresis, micturition disturbances or polyuria
	Less frequent	Pollakiuria, urinary retention, dysuria, urinary incontinence
Pregnancy, puerperium, and perinatal conditions	*Frequency unknown*	Drug withdrawal syndrome in neonates*
Reproductive system and breast disorders	*Less frequent*	Erectile dysfunction, ejaculatory dysfunction, orgasmic dysfunction, priapism, gynaecomastia, galactorrhoea, disturbances in the menstrual cycle, amenorrhoea, sexual dysfunction, breast pain, breast discomfort, breast enlargement, breast discharge, vaginal discharge
	Frequency unknown	Priapism*
General disorders and administration site conditions	*Frequent*	Fatigue, pyrexia, chest pain, asthenia, peripheral oedema
	Less frequent	Chills, increase in body temperature, abnormal gait, thirst, chest discomfort, malaise, feeling abnormal, discomfort, decrease in body temperature, peripheral coldness, drug withdrawal syndrome, face oedema, influenza-like illness, sluggishness
	Frequency unknown	Induration, hypothermia*
Investigations	*Frequent*	Increased blood prolactin, increased weight
	Less frequent	Abnormal electrocardiogram, increased blood glucose, increased transaminases, decreased white blood cell count, increased body temperature, increased eosinophil count, decreased haemoglobin, increased blood creatine phosphokinase, decreased body temperature
Injury and poisoning	*Frequent*	Fall
	Less frequent	Procedural pain

*Post marketing adverse events

c. Description of selected adverse reactions
Extrapyramidal disorder may occur: Parkinsonism (salivary hypersecretion, musculoskeletal stiffness, parkinsonism, drooling, cogwheel rigidity, bradykinesia, hypokinesia, masked facies, muscle tightness, akinesia, nuchal rigidity, muscle rigidity, parkinsonian gait, and glabellar reflex abnormal), akathisia (akathisia, restlessness, hyperkinesia, and restless leg syndrome), tremor, dyskinesia (dyskinesia, muscle twitching, choreoathetosis, athetosis, and myoclonus), dystonia.
Dystonia includes dystonia, muscle spasms, hypertonia, torticollis, muscle contractions involuntary, muscle contracture, blepharospasm, oculogyration, tongue paralysis, facial spasm, laryngospasm, myotonia, opisthotonus, oropharyngeal spasm, pleurothotonus, tongue spasm, and trismus. Tremor includes tremor and parkinsonian rest tremor. It should be noted that a broader spectrum of symptoms are included, that do not necessarily have an extrapyramidal origin.

d. Paediatric population
The following ADRs were reported with a frequency ≥ 5 % in paediatric patients (5 - 17 years) and with at least twice the frequency seen in clinical trials in adults: somnolence/sedation, fatigue, headache, increased appetite, vomiting, upper respiratory tract infection, nasal congestion, abdominal pain, dizziness, cough, pyrexia, tremor, diarrhoea, and enuresis.
The safety and efficacy of ZOXADON ODT in children under 5 years of age has not been demonstrated.

e. Other special populations
Elderly patients with dementia:
Transient ischaemic attack and cerebrovascular accident were ADRs reported in clinical trials with a frequency of 1,4 % and 1,5 %, respectively, in elderly patients with dementia. In addition, the following ADRs were reported with a frequency ≥ 5 % in elderly patients with dementia and with at least twice the frequency seen in other adult populations: urinary tract infection, peripheral oedema, lethargy, and cough.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.
An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

4.9 Overdose
Signs and symptoms:
Reported signs and symptoms have been those resulting from an exaggeration of ZOXADON ODT's known pharmacological effects. Symptoms of acute overdosage include drowsiness, sedation, hypotension, tachycardia and extrapyramidal symptoms. In overdose, cases of QT-prolongation and convulsions have been reported. Torsade de pointes has been reported in association with combined overdose of oral risperidone and paroxetine. In the case of acute overdosage, the possibility of multiple medicine involvement should be considered.

Management of overdose:
Establish and maintain a clear airway and ensure adequate oxygenation and ventilation. Administration of activated charcoal together with a laxative should be considered. Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible dysrhythmias. Since there is no known antidote if accidental poisoning or overdosage is suspected, appropriate supportive measures should be instituted. Hypotension and circulatory collapse should be treated with appropriate measures such as intravenous fluids and/or sympathomimetic medicines. In case of severe extrapyramidal symptoms, anticholinergic medicine should be administered. Close medical supervision and monitoring should continue until the patient recovers.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: other antipsychotics
ATC code: N05AX08
Pharmacological classification: A.2.6.5 Central nervous system depressants. Miscellaneous structures.

Mechanism of action
Risperidone is an antipsychotic of the benzisoxazole derivatives. It is a selective monoaminergic antagonist. Risperidone has affinity for serotonin-5-HT2, dopamine-D2, H1-histamine, alpha1- and alpha2-adrenergic receptors. Risperidone has no affinity for cholinergic receptors. It is a potent D2 antagonist.

5.2 Pharmacokinetic properties
Absorption:
ZOXADON ODT disintegrates in the oral cavity, releasing risperidone into saliva prior to swallowing. After ingestion, risperidone is released into the gastrointestinal tract and is available for absorption.
Risperidone is completely absorbed after oral administration. Food does not affect the absorption of risperidone.

Distribution:
Peak plasma concentrations are attained within 1 - 2 hours. Steady state is reached within 1 day for risperidone in most patients and 4 - 5 days for 9-hydroxyrisperidone.

Biotransformation:
Risperidone is metabolised by cytochrome CYP2D6 to 9-hydroxyrisperidone which has a similar pharmacological activity to risperidone. Risperidone and 9-hydroxyrisperidone form the active antipsychotic fraction. After oral administration, the half-life of risperidone is about 3 hours. The elimination half-life of 9-hydroxyrisperidone and the active antipsychotic fraction is 24 hours. Following 6 mg or 8 mg once daily, peak levels of the active moiety are about 30 % higher and trough levels about 30 % lower than the peaks and troughs following 3 mg and 4 mg twice daily.
Risperidone is bound to albumin and alpha1-acid glycoprotein. Plasma protein binding of risperidone is 88 %, and 77 % for 9-hydroxyrisperidone.

Elimination:
One week after administration, 70 % of the dose is excreted in the urine and 14 % in the faeces. In urine, risperidone and 9-hydroxyrisperidone represent 35 - 45 % of the dose.

Linearity/non-linearity:
Risperidone plasma concentration is dose-proportional within the therapeutic dose-range.

Pharmacokinetics in special patient groups
Risperidone shows significantly higher active plasma concentrations and slower elimination in the elderly and in patients with moderately severe renal insufficiency. The plasma concentrations of risperidone are normal in patients with mild to moderate liver insufficiency.
Irrespective of the indication, starting and consecutive dosing should be halved, and dose titration should be slower for patients with renal or hepatic impairment.
Risperidone should be used with caution in these groups of patients.

Paediatric population
The pharmacokinetics of risperidone, 9-hydroxyrisperidone and the active moiety in children are similar to those in adults.

5.3 Preclinical safety data
Not applicable.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Aspartame
Basic butylated methacrylate copolymer
Calcium silicate
Crospovidone
Flavour peppermint
Flavour spearmint
Hydroxypropyl cellulose
Iron oxide red
Magnesium stearate
Mannitol
Microcrystalline cellulose
Povidone

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store below 30°C. Protect from moisture and light.
Keep the blisters in the carton until required for use.

6.5 Nature and contents of container
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.

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House
Steenberg Office Park
Silverwood Close
Westlake, 7945
Cape Town
South Africa
Tel.: +27 21 707 7000
or 0860-PHARMA (742 762)

8. REGISTRATION NUMBERS
ZOXADON ODT 0,5 mg: A46/2.6.5/0362
ZOXADON ODT 1 mg: A46/2.6.5/0363
ZOXADON ODT 2 mg: A46/2.6.5/0364

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
15 May 2019

10. DATE OF REVISION OF THE TEXT
07 November 2024

PATIENT INFORMATION LEAFLET

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 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

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 may be 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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Registration numbers
ZOXADON ODT 0,5 mg: A46/2.6.5/0362
ZOXADON ODT 1 mg: A46/2.6.5/0363
ZOXADON ODT 2 mg: A46/2.6.5/0364

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S5

ZOXADON ODT 0,5 mg oraal-disintegrerende tablette
ZOXADON ODT 1 mg oraal-disintegrerende tablette
ZOXADON ODT 2 mg oraal-disintegrerende tablette
Risperidoon
ZOXADON ODT bevat versoeter (aspartaam) in die volgende hoeveelhede:
0,4 mg, 0,8 mg, en 1,6 mg g per 0,5 mg, 1 mg en 2 mg tablet, onderskeidelik.
ZOXADON ODT bevat suiker
(mannitol 27,8 mg, 55,6 mg en 111,2 mg per 0,5 mg, 1 mg en 2 mg tablet, onderskeidelik).

Lees hierdie hele inligtingsblad deeglik deur, voordat u begin om ZOXADON ODT te neem
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige, of ander gesondheidsorgverskaffer.
- ZOXADON ODT is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as u eie.

Inhoud van hierdie inligtingsblad
1. Wat ZOXADON ODT is en waarvoor dit gebruik word
2. Wat u moet te weet, voordat u ZOXADON ODT neem
3. Hoe om ZOXADON ODT te neem
4. Moontlike newe-effekte
5. Hoe om ZOXADON ODT te bewaar
6. Verpakkingsinhoud en ander inligting

1. Wat ZOXADON ODT is en waarvoor dit gebruik word
ZOXADON ODT bevat risperidoon, een van 'n groep medisyne wat antipsigotiese medisyne genoem word.

ZOXADON ODT word gebruik vir:
- skisofrenie: waar u dinge mag sien, hoor of voel, wat nie daar is nie, dit moeilik vind om helder te dink, u emosies te beheer, aanklank te vind by ander en normaal te funksioneer, u mag aan delusies ly, vyandiggesind en agterdogtig wees, emosionele gevoelloosheid, emosionele en sosiale onttrekking en dit moeilik vind om te kommunikeer. ZOXADON ODT kan help om die simptome van u toestand te verlig en verhoed dat u simptome terugkeer
- gedragsprobleme by kinders (ouderdom 5 -12 jaar oud), met ondergemiddelde intellektuele funksionering, of verstandelike gestremdheid – soos aggressie, impulsiwiteit en selfbesering. Die gewig van die kind moet 50 kg of meer wees, voordat ZOXADON ODT gebruik word
- manie en bipolêre versteuring. Hierdie gevalle word gekenmerk deur simptome soos verhoogde, omvattende of prikkelbare gemoedstoestand, oordrewe selfbeeld, verminderde behoefte aan slaap, onderdrukte spraak, vlugtende gedagtes, afleibaarheid, of swak oordeel, insluitend ontwrigtende, of aggressiewe gedrag.

2. Wat u moet weet, voordat u ZOXADON ODT neem
Moet nie ZOXADON ODT neem:
- indien u hipersensitief (allergies) is vir risperidoon, of vir enige van die ander bestanddele van ZOXADON ODT nie (sien afdeling 6)
- indien u swanger is, of borsvoed nie (sien Swangerskap en borsvoeding)
- indien u aan Lewy-liggaam demensie ('n tipe demensie verwant aan Alzheimer se siekte), of Parkinson se siekte, ly nie
- moet nie ZOXADON ODT aan kinders jonger as 5 jaar, met gedragsversteuring en ander ontwrigtende gedragsversteurings gee nie.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met ZOXADON ODT:
- indien u gediagnoseer is met demensie, wat verband hou met Parkinson se siekte en seniele demensie (sien Moet nie ZOXADON ODT neem)
- indien u tans furosemied neem (om hoë bloeddruk en swelling wat veroorsaak word deur 'n oormaat vloeistof in die liggaam, te behandel), aangesien daar 'n verhoogde risiko is vir erge dehidrasie, of sterfte by bejaarde persone met demensie
- indien u nierprobleme het (tekens sluit naarheid, braking, aptytverlies, uiterste moegheid, swakheid, slaapprobleme en veranderinge in hoe dikwels u urineer, in
- indien u lewerprobleme het (tekens sluit buikpyn, naarheid of braking, uiterste moegheid, donkerkleurige urine, geen eetlus, jeukerige vel, vel en oë wat gelerig voorkom (geelsug), swelling in die bene en enkels, bleek, bloederige of teer-kleurige ontlasting, geneigdheid om maklik te kneus, in)
- indien u simptome van tardiewe diskinesie ondervind (hierdie sluit stywe, rukkerige bewegings van die tong, mond, gesig en liggaam in, wat u nie in staat is om te beheer nie)
- indien u 'n psigo-stimulant neem (medisyne wat gebruik word vir aandaggebrek-hiperaktiwiteitsteuring (AGHS) soos metielfenidaat), aangesien u ongunstige newe-effekte mag ervaar, wanneer die dosis van enige een van die medisyne aangepas word
- indien u simptome van neuroleptiese maligne sindroom (NMS) ervaar (dit sluit hoë temperatuur, spierstyfheid, sweet, afname in bewussynsvlak, vinnige of onreëlmatige hartklop, in)
- indien u simptome van prolaktinemie ervaar (abnormaal hoë vlakke van die hormoon prolaktien, in u bloed) (hierdie sluit onderontwikkeling van borste by mans, probleme om 'n ereksie te verkry en te behou; by vroue ongemak of lekkasie van melk vanuit die borste, siklusse wat oorgeslaan word, of ander probleme met die menstruele siklus, in)
- indien u aan hoë bloedsuikervlakke, of diabetes ly, aangesien u bloedsuikervlakke mag vererger, of u mag 'n risiko vir diabetes toon (bv. vetsug, familiegeskiedenis van diabetes), of u is voortdurend dors en honger, urineer meer as wat normaal is vir u en voel swak
- indien u 'n beroerte gehad het, of aan enige toestand ly wat mag lei tot 'n beroerte, soos hoë bloeddruk, hartversteuring, of bloedvatprobleme in die brein
- indien u hartprobleme, of 'n familiegeskiedenis van hartsiekte het, insluitend hartversaking, hartaanvalle, onreëlmatige harttempo, u geneig is om te dehidreer, of u ervaar lae bloeddruk (voel lighoofdig of duiselig, wanneer u opstaan vanuit 'n lêende of sittende posisie). Dit mag nodig wees om u ZOXADON ODT dosis aan te pas
- indien u 'n geskiedenis van lae witbloedselvlakke het (wat dalk mag, of nie mag veroorsaak word deur ander medisyne nie)
- indien u 'n oogoperasie beplan, aangesien die gekleurde gedeelte van u oog, slap mag word tydens die operasie en die risiko vir oogprobleme tydens en na 'n katarak operasie, mag verhoog
- indien u aan epilepsie of aanvalle (stuipe) ly, mag ZOXADON ODT die simptome van hierdie toestande vererger
- indien u 'n man is en u 'n voortdurende of pynlike ereksie ervaar
- indien u probleme ervaar om u liggaamstemperatuur te beheer, of oorverhit in situasies soos veeleisende oefening, uiterste hitte, die neem van ZOXADON ODT saam met ander medisyne, of wanneer u gedehidreer is
- indien ZOXADON ODT u verhoed om te braak
- ZOXADON ODT mag gewigstoename veroorsaak. Beduidende gewigstoename, mag u gesondheid negatief beïnvloed. U dokter moet u liggaamsgewig gereeld bepaal
- indien u, of iemand in u familie, 'n geskiedenis van bloedklonte het.

Bejaardes met demensie:
Daar is 'n toenemende risiko van beroerte in bejaardes met demensie. U moet nie ZOXADON ODT neem indien u demensie, veroorsaak deur 'n beroerte, het nie. U moet gereeld u dokter gaan sien tydens behandeling met ZOXADON ODT. Mediese behandeling moet dadelik aangevra word as u versorger 'n skielike verandering in u geestestoestand of skielike swakheid of gevoelloosheid van u gesig, arms of bene, veral aan die een kant, of onduidelike spraak opmerk, selfs vir 'n kort tydperk.

Studies in bejaarde pasiënte met demensie het getoon dat ZOXADON ODT, geneem met of sonder furosemied, geassosieer word met 'n hoër sterftesyfer. Vertel u dokter as u furosemied neem. Furosemied is 'n medisyne wat soms gebruik word om hoë bloeddruk, sommige hartprobleme, of om swelling van dele van die liggaam, wat veroorsaak word deur die opbou van te veel vloeistof, te behandel.

Kinders en adolessente:
- indien u kind/adolessent, terwyl ZOXADON ODT gebruik word, enige van die volgende ondervind: slaperigheid, moeilike konsentrasie en leervermoë, abnormale groei en ontwikkeling, of abnormale liggaamsbewegings
- voor behandeling begin word, moet u of u kind se liggaamsgewig bepaal word en dit moet gereeld tydens behandeling, gemonitor word.

'n Klein, onbeslissende studie het 'n toename in liggaamsgewig by kinders wie risperidoon neem, aangemeld, maar of dit 'n effek van ZOXADON ODT is, of weens 'n ander rede, is onbekend.

Ander medisyne en ZOXADON ODT
Vertel altyd u gesondheidsorgverskaffer, indien u enige ander medisyne neem (Dit sluit aanvullende, of tradisionele medisyne in).

Dit is veral belangrik om u dokter te vertel indien u enige van die volgende medisyne neem, wat die funksionering van u hart mag aantas:
- hartmedisyne wat 'n abnormale hartklop behandel – kinidien, disopiramied, prokaïenamied, propafenoon, amiodaroon, sotalol
- antidepressie medisyne – amitriptilien en maprotilien
- sommige antihistamien medisyne (vir allergie) bv. terfenadien, astemisool
- malaria medisyne – kinien en meflokien
- ander antipsigotiese medisyne
- medisyne wat verlaging van kaliumvlakke (bv. hidrochloortiasied, furosemied) en magnesiumvlakke (bv. furosemied), veroorsaak.

Dit is ook belangrik om u dokter te vertel indien u enige van die volgende medisyne neem:
- opiate vir pyn (bv. metadoon), antihistamiene vir allergie (bv. prometasien), bensodiasepiene vir angstigheid (bv. diasepam, alprasolam) saam met ZOXADON ODT, kan lei tot 'n toenemende gevoel van lomerigheid
- levodopa en ander medisyne in hierdie klas (om Parkinson se siekte te behandel)
- bloeddrukverlagende medisyne (bv. enalapril, lisinopril, valsartan, telmisartan)
- paliperidoon (om skisofrenie te behandel)
- fluoksetien en paroksetien (om depressie te behandel)
- sertralien (om depressie en paniekteurings te behandel) en fluvoksamien (om obsessief-kompulsiewe steuring te behandel)
- verapamil (om hoë bloeddruk, angina en harttoestande te behandel)
- simetidien en ranitidien (blokkeerders van maagsuur)
- itrakonasool en ketokonasool (swamwerende behandeling)
- ritonavir (anti-MIV (menslike immuniteitsgebreksvirus) medisyne)
- karbamasepien, fenitoïen en fenobarbitoon (om tipes epileptiese aanvalle te beheer)
- rifampisien (tuberkulose (TB) behandeling).

ZOXADON ODT mag 'n uitwerking op die volgende medisyne uitoefen:
- furosemied (watertablette) saam met ZOXADON ODT mag 'n verhoogde risiko vir sterftes by bejaarde pasiënte met dimensie tot gevolg hê (sien Neem spesiale sorg met ZOXADON ODT)
- valproaat (om manie by pasiënte met bipolêre versteuring te beheer)
- topiramaat (om aanvalle te behandel en migraines by volwassenes, te verhoed)
- fenotiasiene (om u te kalmeer)
- aripiprasool (om senuweetoestande te behandel)
- amitriptilien, imipramien en venlafaksien (om depressie te behandel)
- metielfenidaat (behandeling van gedrags- en slaapversteurings by adolessente en kinders)
- quetiapien (om skisofrenie en bipolêre versteuring te behandel)
- klosapien (om erge skisofrenie te behandel)
- litium (om manie en gevalle van maniese depressie te behandel)
- eritromisien (om baie verskillende tipe infeksies wat veroorsaak word deur bakterieë, te verhoed)
- donepesil of galantamien (om lig tot matige demensie, wat deur Alzheimer se siekte veroorsaak word, te behandel)
- diasepam (om angsversteurings te behandel)
- warfarien (om bloedklonte te verhoed)
- digoksien (om hartversaking en hartritmeversteurings te behandel)
- sommige betablokkers bv. propranolol (om bewing, borspyn, hoë bloeddruk en ander harttoestande, te behandel).

ZOXADON ODT saam met kos, drinkgoed en alkohol
U kan ZOXADON ODT mét, of sonder kos neem.
U moet alkoholinname vermy, terwyl ZOXADON ODT geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien u swanger is of u baba borsvoed, vermoed dat swanger is, of 'n baba beplan, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgverskaffer vir advies, voordat u ZOXADON ODT gebruik.

Die veiligheid van ZOXADON ODT vir swanger vroue en die wie borsvoed, is nie vasgestel nie (sien moet nie ZOXADON ODT neem).

Swangerskap
Die volgende simptome mag by pasgebore babas, van moeders wie ZOXADON ODT tydens die laaste trimester (laaste drie maande van hulle swangerskap) gebruik het, voorkom: bewing, spierstyfheid en/of swakheid, slaperigheid, agitasie, asemhalingsprobleme en moeilike voeding. Indien u baba enige van hierdie simptome ontwikkel, mag dit nodig wees om u dokter te kontak.

Borsvoeding
Hierdie medisyne word in borsmelk uitgeskei. U moet nie hierdie medisyne neem, terwyl u u baba borsvoed nie.

Fertiliteit
ZOXADON ODT mag u vlakke van die hormoon wat "prolaktien" genoem word, verhoog. Dit mag fertiliteit by beide vroulike en manlike pasiënte aantas.

Bestuur en die hantering van masjiene
ZOXADON ODT mag slaperigheid, duiseligheid en 'n verlies van konsentrasie veroorsaak. Moet nie bestuur, of masjiene hanteer, voordat u weet hoe ZOXADON ODT u aantas nie.
Dit is nie altyd moontlik om te voorspel tot watter mate ZOXADON ODT met die daaglikse aktiwiteite van 'n pasiënt sal inmeng nie. Pasiënte moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak, totdat hulle weet tot watter mate ZOXADON ODT hulle beïnvloed nie.

Belangrike inligting omtrent sommige van die bestanddele van ZOXADON ODT:
ZOXADON ODT bevat aspartaam. Aspartaam is 'n bron van fenielalanien. Dit kan skadelik wees as u fenielketonurie (PKU) het, 'n seldsame genetiese afwyking waarin fenielalanien opbou omdat die liggaam dit nie behoorlik kan verwyder nie.

3. Hoe om ZOXADON ODT te neem
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Gebruik ZOXADON ODT altyd presies soos deur u dokter aangedui word. U moet u dokter of apteker raadpleeg, indien u onseker is.

U dokter sal die gepaste dosering, in ooreenstemming met u toestand, bepaal.

U dokter sal vir u vertel hoe lank u behandeling met ZOXADON ODT sal duur. Indien u onder die indruk is dat die effek van ZOXADON ODT té sterk, of té swak is, vertel u dokter of apteker.

Besonderhede vir die gebruik van ZOXADON ODT:
Verwyder slegs een tablet vanuit die stulpstrook, wanneer dit tyd is om u medisyne te neem. Trek die stulpstrook oop, om die tablet te ontbloot.
Moet nie die tablet deur die foelie druk nie, aangesien die tablet broos is en mag breek.
Verwyder die tablet vanuit die stulpstrook met skoon, droë hande en plaas dit dadelik op u tong.
Die tablet sal onmiddellik begin disintegreer. Dit kan dan mét of sonder water ingesluk word.
Indien dit saam met voedsel geneem word, moet die mond leeg wees, voordat die tablet op die tong geplaas word.

Indien u meer ZOXADON ODT neem as wat u behoort
In die geval van oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kontak die naaste hospitaal, of gifbeheersentrum.

Simptome van oordosering mag die volgende insluit:
- u mag slaperig of moeg voel, of abnormale liggaamsbewegings ervaar, probleme ondervind om te staan of te loop, duiselig voel weens lae bloeddruk, of abnormale hartklop of stuipe ondervind.

Indien u vergeet om ZOXADON ODT te neem
- indien u 'n dosis oorgeslaan het, neem dit so gou as wat u onthou.
- indien dit amper tyd is vir die volgende dosis, slaan die vergete dosis oor en gaan voort om die tablet op die gewone tydstip te neem.
- moet nie 'n dubbeldosis neem, om op te maak vir die vergete individuele dosisse nie.
- indien u dit moeilik vind om te onthou wanneer om ZOXADON ODT te neem, vra u apteker vir 'n paar wenke wat mag help.

Indien u die behandeling met ZOXADON ODT staak
U moet nie die gebruik van ZOXADON ODT staak, tensy u dokter so aanbeveel nie. U simptome mag terugkeer en u mag onttrekkingsimptome soos sweet, naarheid en braking ervaar. Indien u dokter besluit om ZOXADON ODT te staak, sal u dosis geleidelik, oor etlike dae, verlaag word.

4. Moontlike newe-effekte
ZOXADON ODT kan newe-effekte hê.
Nie alle newe-effekte wat vir ZOXADON ODT aangemeld is, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid versleg, of indien u enige ongunstige effekte ervaar terwyl u ZOXADON ODT gebruik raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van ZOXADON ODT en vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat sluk en asemhaling mag bemoeilik
- uitslag of gejeuk
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ondervind, kon u 'n ernstige allergiese reaksie teenoor ZOXADON ODT ervaar het. U mag dringende mediese aandag, of hospitalisasie benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- 'n bloedklont in 'n aar (simptome sluit swelling, pyn en rooiheid van die bene, in)
- blokkade van 'n longarterie (simptome sluit skielike borspyn, tesame met moeilike asemhaling, in)
- u ervaar koors, spierstyfheid, sweet, of 'n afname in bewussynsvlak ('n versteuring wat neuroleptiese maligne sindroom genoem word)
- u 'n man is, en 'n langdurige, of pynlike ereksie ervaar. Dit word priapisme genoem
- u herhaaldelike liggaamsbewegings ervaar, insluitend grynsing, onbeheerbare tonguitsteek, of lipsmak, beroerte (algemene simptome is skielike gevoelloosheid, tinteling, swakheid, of bewegingsverlies in u gesig, arm, of been, veral aan slegs die een kant van u liggaam), bewussynsverlies floute, voel uiters rusteloos, vind dit moeilik om balans te handhaaf, voel duiselig, spraakprobleme, afname in stimuli-sensitiwiteit, "spelde en naalde" gevoel, diabetiese koma (hoë bloedsuiker), steiering/struikeling, of kop wat geskud word. Hierdie is tekens of probleme met u senuweestelsel
- indien die oog-iris slap word, na 'n katarak operasie
- vinnige harttempo, abnormale hartritme, hoë bloeddruk, asemnood, borspyn
- vergeling van die vel en die wit gedeeltes van die oë (geelsug), wat tekens van lewerprobleme is.

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter indien u enige van die volgende opmerk:
Algemene newe-effekte:
- urienweg- en boonste lugweginfeksies, brongitis, influensa en pneumonie
- verhoogde vlakke van 'n hormoon, wat prolaktien genoem word en deur 'n bloedtoets bepaal word. Dit mag dalk, of dalk nie, lei tot die volgende simptome by mans: swelling van die borste, vind dit moeilik om ereksies te verkry, of te behou, of ander seksuele wanfunksie; by vroue: ongemak in die borste, lekkasie van melk vanuit die borste, menstruele siklusse word oorgeslaan, of ander probleme met u siklus
- gewigstoename, toename of afname in eetlus
- slaaploosheid, agitasie, angstigheid, konsentrasieverlies, geheueprobleme, gemoedsversteurings, aggressiewe optrede, voel depressief
- hoofpyn, duiseligheid, sedasie, toename in droomaktiwiteit, lomerigheid, bewegingsabnormaliteite, soos bewing, stadige beweging, moeilike spraak, spierstyfheid, buitensporige speekselvloei, stadige beweging, beweging van die oogballe na 'n vaste posisie (gewoonlik opwaarts), spiertrilling, rusteloosheid en onvermoë om stil te sit, onwillekeurige spiersametrekkings, wat herhalende kronkelbewegings veroorsaak, spiertrekkings
- wasige sig
- hipertensie (hoë bloeddruk)
- asemnood, rinitis (toe, loperige, of jeukerige neus, genies), hoes, pynlike, of seer keel, neusbloeding
- hardlywigheid, indigestie, of omgekrapte maag, naarheid droë mond, diarree, braking, maagpyn, maagongemak, tandpyn, afname in speekselvloei
- rooi, of jeukerige vel, veluitslag
- rug-, gewrigs- of spierpyn, spierkrampe, pyn in die hande en/of voete
- bednatmaak snags, urineer dikwels, of die onvermoë om te urineer, urineer meer as wat normaal is vir u
- moegheid, energietekort, koors, borspyn, geswelde hande en onderste gedeeltes van die bene
- val gereeld.

Minder algemene newe-effekte:
- oor- en lugweginfeksie (bv. brongitis, pneumonie en griep), blaas-, oog en velinfeksies, tonsillitis, virusinfeksies, swaminfeksie van die naels, akarodermatitis (inflammasie van vel, hande of voete), sinusitis, voortdurende, chronies infeksie van die middel-oor
- afname in die tipe witbloedsel, wat help om u teen infeksie te beskerm, afname in bloedplaatjies (bloedselle wat help om bloeding te stop), anemie ('n afname in rooibloedselle; simptome sluit bleekheid, moegheid en swakheid in), toename in eosinofille ('n tipe witbloedsel) in u bloed
- uitermatige waterinname, teenwoordigheid van glukose in die urine
- lae en hoë bloedsuikervlakke, hoër as normale insulienvlakke in die bloed, abnormale dors, gewigstoename, anoreksie
- hipomanie (hoë energievlakke, uitermatige geesdrif, afname in die behoefte om te slaap), voel verward of senuweeagtig, afname in seksdrang, nagmerries, verlies van emosie, lusteloosheid
- oë is ligsensitief, droë oë, toename in traanvorming vanuit die oë, oogpyn met sigsteurnisse, oormaat bloed in die wit gedeeltes van die oë (rooi oë), verhoging in oogdruk (gloukoom), oogbewegingversteuring, oogrolling, inflammasie van die ooglid, ooginfeksie (pienk oog), oogswelling, oogafskeiding, sigverlies wat nie reggestel kan word tot op 'n normale vlak, met 'n bril nie
- vertigo (voel lighoofdig, of duiselig), tinnitus (gelui in die ore), oorpyn
- lae bloeddruk (voel lighoofdig, of duiselig), insluitend wanneer u opstaan vanuit 'n sittende of lêende posisie, vel blosvorming
- pneumonie aspirasie (inflammasie van die longe, veroorsaak deur die inaseming van voedsel), inflammasie van die mukusmembrane en sinusse, boonste lugweginfeksies (neus, sinusse, agterkant van die keel, stembande), hiperventilasie (baie vinnige asemhaling), ratelende klank in die longe, heesheid en verandering in die stemtoon, of -kwaliteit
- verhoging in speekselvorming in die mond, onvermoë om ontlasting te beheer, harde stoelgang, gastroenteritis, maaggriep (algemene simptome is naarheid, braking en maagpyn), vind dit moeilik om te sluk, oormaat wind, geswelde tong/lippe, inflammasie van die lippe
- toename in lewertransaminase in u bloed, toename in GGT ('n lewerensiem wat gamma-glutamieltransferase genoem word) in u bloed, toename in lewerensieme in u bloed
- droë vel, toename in velpigmentasie (verdonkering van die vel), toename in sweet, ekseem (ontsteekte, jeukende, rooi, gekraakte en growwe vel), olierigheid van die vel, verdikking van die vel, velletsels, oorsensitiwiteit van die vel vir lig, urtikarie, jeukende en erge veluitslag, velreaksie, skilfers, velverkleuring, swelling van die dieper vellae, wat veroorsaak word deur vog wat opbou
- abnormale postuur, gewrigstyfheid, gewrigswelling, spierswakheid, nekpyn, spierpyn
- tekens van moontlike spierweefselbesering, insluitend spierpyn, swakheid, braking, verwarring en bloedtoetse wat 'n verhoging in bloedkreatienfosfokinase aandui
- drang om meer gereeld deur die dag te urineer, onvermoë om te urineer, pyn tydens urinering, verlies van blaasbeheer
- seksuele probleme by mans, insluitend die onvermoë om 'n ereksie te verkry of te behou, vind dit moeilik om 'n orgasme te bereik, of te ejakuleer, oorontwikkeling van borste
- uitskeiding van borsmelk by mans en vroue wie nie borsvoed nie
- seksuele probleme by vroue, insluitend om moeilik 'n orgasme te bereik, verandering in menstruele siklus, pyn in die borste, of borstevergroting, ongemak in die borste en vaginale afskeiding
- koue rillings, verhoging in liggaamstemperatuur, stap abnormaal, dors, borsongemak, algemene gevoel van ongesteldheid of ongemak, influensa-soortige siekte
- u ondervind probleme om u liggaamstemperatuur te beheer, of oorverwarming
- skielike afname in liggaamstemperatuur, koue hande/voete, onttrekkingseffekte wanneer u die gebruik van ZOXADON ODT staak, insluitend sweet, naarheid, braking, of die terugkeer van 'n toestand waarvoor ZOXADON ODT behandeling benodig word (sien Effekte wanneer behandeling met ZOXADON ODT gestaak word)
- bloedtoetse wat abnormale nierfunksie en lewerfunksie, spierbesering, bloedsuiker, rooi- en witbloedselvlakke aandui, afname in liggaamstemperatuur
- pyn wanneer prosedure uitgevoer word, bv. wondsorg.

Die volgende newe-effekte is aangemeld, maar die frekwensie van voorkoms is onbekend:
- bloedtoetsresultate wat ernstig lae witbloedselvlakke aandui (agranulositose)
- diabetes of, verergering van diabetes (met simptome soos buitensporige dors, toename in urinering, konstante honger), bloedcholesterol neem toe, lae bloedsuikervlakke
- manie (tydperke van groot opwinding, of euforie, delusies en ooraktiwiteit)
- slegte smaak in die mond, 'n toestand van onbeweeglikheid en stupor, slaapverwante eetversteuring
- slaapsteuring, waar asemhaling onwillekeurig ophou en weer begin (dit duur herhaaldelik voort)
- blokkade van die dun- of dikderm, inflammasie van die pankreas (algemene simptome sluit pyn in die bo-buik/maag, naarheid en braking, in)
- haarverlies op die liggaam en hoof
- die volgende simptome mag by pasgebore babas voorkom, indien die moeder ZOXADON ODT tydens die laaste drie maande van swangerskap geneem het: bewing, spierstyfheid en/of swakheid, slaperigheid, agitasie, asemhalingsprobleme en probleme met voeding
- harde knop op die vel, of onder die vel, hipotermie ('n noodgeval wat voorkom wanneer die liggaam hitte vinniger verloor as wat dit hitte kan genereer).

Indien u enige newe-effekte opmerk, wat nie in hierdie inligtingsblad genoem word nie, raadpleeg asseblief u dokter, of apteker.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA via die Med Safety toepassing (Medsafety X SAHPRA) en eReporting platform (who-umc.org), wat op SAHPRA se webtuiste gevind kan word.
Deur die aanmelding van newe-effekte, kan u help om meer inligting aangaande die veiligheid van ZOXADON ODT in te win. U kan ook 'n epos direk aan die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za, om die veiligheid van die produk te verseker.

5. Hoe om ZOXADON ODT te bewaar
Bewaar alle medisyne buite die bereik van kinders.
Bewaar benede 30 °C.
Beskerm teen vog.
Hou stulpstroke in die kartonhouer, totdat dit benodig word vir gebruik.
Moet nie gebruik na die vervaldatum wat op die kartonhouer aangedui word nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in afvoerpype, of rioolstelsels (bv. toilette), weggooi nie.

6. Verpakkingsinhoud en ander inligting
Wat ZOXADON ODT bevat:
Die aktiewe bestanddeel is risperidoon.
ZOXADON ODT 0,5 mg bevat risperidoon 0,5 mg.
ZOXADON ODT 1 mg bevat risperidoon 1 mg.
ZOXADON ODT 2 mg bevat risperidoon 2 mg.

Die ander bestanddele is:
Aspartaam, basies gebutileerde metakrilaatkopolimeer, groenmentgeursel, hidroksiepropielsellulose, kalsiumsilikaat, kruisgekoppelde povidoon, magnesiumsteraat, mannitol, mikrokristallyne sellulose, pepermentgeursel, povidoon en rooi ysteroksied.
ZOXADON ODT bevat die versoeter (aspartaam) in die volgende hoeveelhede: 0,4 mg, 0,8 mg en 1,6 mg per 0,5 mg, 1 mg en 2 mg tablet, onderskeidelik.
ZOXADON ODT bevat suiker (mannitol 27,8 mg, 55,6 mg en 111,2 mg per 0,5 mg, 1 mg en 2 mg tablet, onderskeidelik).

Hoe ZOXADON ODT lyk en die verpakkingsinhoud
ZOXADON ODT 0,5 mg: Ronde (deursnee = 5 mm), effens bikonvekse, pienk gevlekte oraal-dispergerende tablet.
ZOXADON ODT 1 mg: Ronde (deursnee = 6 mm), effens bikonvekse, pienk gevlekte oraal-dispergerende tablet.
ZOXADON ODT 2 mg: Ronde (deursnee = 8 mm), effens bikonvekse, pienk gevlekte oraal-dispergerende tablet.

ZOXADON ODT word verpak in stulpstroke wat bestaan uit koud-gevormde OPA/Al/PVC film en PET/Al aftrek-foelie in verpakkings van 30's in 'n buitenste kartonhouer.

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Registrasienommers
ZOXADON ODT 0,5 mg: A46/2.6.5/0362
ZOXADON ODT 1 mg: A46/2.6.5/0363
ZOXADON ODT 2 mg: A46/2.6.5/0364