PATIENT INFORMATION LEAFLET
ZOXADON TABLETS RANGE

SCHEDULING STATUS:

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

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

ZOXADON 1 mg: Each tablet contains 1 mg risperidone.

ZOXADON 2 mg: Each tablet contains 2 mg risperidone.

ZOXADON 3 mg: Each tablet contains 3 mg risperidone.

ZOXADON 4 mg: Each tablet contains 4 mg risperidone.

Read this entire leaflet carefully before you start taking ZOXADON.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT ZOXADON CONTAINS:

Active ingredient: risperidone.

Inactive ingredients: Lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry white or yellow, and pregelatinised starch.

Contains sugar in the form of lactose monohydrate (See **BEFORE YOU TAKE ZOXADON**).

2. WHAT ZOXADON IS USED FOR:

Risperidone is an atypical antipsychotic.

ZOXADON is indicated for:

- Acute and chronic schizophrenia and related psychosis in which positive symptoms and/or the negative symptoms are prominent.

- Behavioural disturbances in patients with dementia in whom symptoms such as aggressiveness, activity disturbances or psychotic symptoms are prominent.
- Conduct and other disruptive behaviour disorders in children (aged 5 - 12 years), with subaverage intellectual functioning or mental retardation in whom destructive behaviours are prominent.
-

3. BEFORE YOU TAKE ZOXADON:

Do not take ZOXADON:

- If you are hypersensitive (allergic) to risperidone, or to any of the other ingredients of **ZOXADON**.
- If you are pregnant or breastfeeding your baby.
- Do not give this medicine to children under 5 years with conduct and other disruptive behaviour disorders.

Take special care with ZOXADON:

Tell your doctor:

- If you suffer from kidney or liver function impairment.
- If you suffer from Parkinson's disease: muscle weakness, muscle stiffness, impaired and slow movement and shaking. **ZOXADON** may worsen the symptoms of these conditions.
- If you suffer from epilepsy: fits / seizures. **ZOXADON** may worsen the symptoms of this condition.
- If you have a condition called tardive dyskinesia: characterised by jaw movements, chewing-like movements, tongue movements, smacking of the lips or involuntary rapid arm or leg movements.
- If you experience any of the following symptoms of neuroleptic malignant syndrome: muscle spasms, irregular pulse or blood pressure, high fever, irregular heart rate,

increased heart rate and increased sweating (perspiration).

- If you take furosemide water tablets.
- If you have diabetes: high blood sugar.
- If you have a history of cerebrovascular adverse events: strokes.
- If you suffer from heart disease or have low blood pressure.
- If you have a history of galactose intolerance (a simple sugar found in lactose) or impaired absorption of glucose-galactose.
- If you are old aged or suffer from dementia (progressive intellectual impairment) associated with Parkinsonism.
- If you are planning to have an eye operation, intraoperative floppy iris syndrome may increase the risk of eye complications during and after cataract surgery.

  If you have a tendency to over-eat or gain weight easily.

Pregnancy and breastfeeding:

The safety of **ZOXADON** in pregnant and breast-feeding women has not yet been established. If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Driving and using machines:

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

Using other medicines with ZOXADON:

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

Do not take alcohol and **ZOXADON** simultaneously.

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

sleeping tablets).

ZOXADON may cause levodopa and other dopamine agonists (used to treat Parkinson's disease) to be less effective.

Chronic administration of carbamazepine and clozapine may decrease the plasma levels of **ZOXADON**.

Fluoxetine and paroxetine (an antidepressant medicine) may increase the plasma concentration of **ZOXADON**.

Tell your doctor if you are using any medication that will cause your blood pressure to fall. Concomitant use of such medication and **ZOXADON** may, cause very low blood pressure.

4. HOW TO TAKE ZOXADON:

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

Treatment of schizophrenia:

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

You may take **ZOXADON** either once daily or twice daily.

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

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

Liver and kidney impairment:

Your doctor should halve both the starting dose and the subsequent dose increments if you

suffer for liver or kidney impairment.

Elderly patients:

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

Treatment of behavioural disturbances in patients with dementia

The usual starting dose is 0,25 mg twice daily. Your doctor may increase the dose to a maintenance dose of 0,5 mg to 1 mg twice daily.

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

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

If you take more ZOXADON than you should:

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

If you forget to take ZOXADON:

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

5. POSSIBLE SIDE EFFECTS:

ZOXADON can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine please consult your doctor, pharmacist or other health care professional for advice.

PATIENT INFORMATION LEAFLET
ZOXADON TABLETS RANGE

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

Less frequent occurrence

- Fast or irregular heart beat
- Difficult or unusually fast breathing, high fever, irregular blood pressure, toss of bladder control, severe muscle stiffness, seizures, unusual pale skin, tiredness of weakness.
- Cough difficulty swallowing, dizziness, hives, itching, tightness in chest, wheezing and puffiness or swelling of eyelids, face, lips or tongue.

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

Tell your doctor if any of the following side effects occur:

Frequent occurrence

- Restlessness or need to keep moving
- Anxiety or nervousness
- Muscle spasm of face, neck and back, twitching movements, weakness of arms or legs
- Difficulty in speaking or swallowing, loss of balance control, trembling and shaking of hands and fingers
- Insomnia; asthenia; fatigue; lassitude; drowsiness; headache; increased dream activity; increased duration of sleep
- Changes in vision
- Constipation, diarrhoea; dyspepsia; vomiting; nausea
- Skin rash or itching
- Problems in urination or increase in amount of urine

- Mood or mental changes, including aggressive behaviour, agitation, difficulty in concentration and memory problems
- Sexual dysfunction or decrease libido; menstrual changes

Less frequent occurrence

- Back pain
- Menstrual changes; unusual secretion of milk; prolonged and painful erection of the penis

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

6. STORING AND DISPOSING OF ZOXADON:

Store at or below 25 °C.

For tablets in blisters: Keep the blisters in the carton until required for use.

For tablets in containers: Keep well closed in the original container.

Do not use the tablets after the expiry date printed on the blister/ container.

Return all unused medicine to your pharmacist

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

STORE ALL MEDICINES OUT OF REACH OF CHILDREN