APPROVED PATIENT INFORMATION LEAFLET

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AUROPERDAL 0.5 mg (Tablet)

AUROPERDAL 1 mg (Tablet)

AUROPERDAL 2 mg (Tablet)

AUROPERDAL 3 mg (Tablet)

AUROPERDAL 4 mg (Tablet)

Risperidone

Read all of this leaflet carefully before you start taking AUROPERDAL.

- 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 AUROPERDAL CONTAINS

The active substance is Risperidone.

AUROPERDAL 0.5 mg: Each film-coated tablet contains 0,5 mg risperidone.

AUROPERDAL 1 mg: Each film-coated tablet contains 1 mg risperidone

AUROPERDAL 2 mg: Each film-coated tablet contains 2 mg risperidone

AUROPERDAL 3 mg: Each film-coated tablet contains 3 mg risperidone

AUROPERDAL 4 mg: Each film-coated tablet contains 4 mg risperidone

The other ingredients are cellulose, microcrystalline; lactose monohydrate; magnesium stearate and silica, colloidal anhydrous.

2. WHAT AUROPERDAL IS USED FOR

AUROPERDAL is used in the treatment of:

- Schizophrenia, where you may see, hear or feel things that are not there, believe things that are not true or feel unusually suspicious, or emotionally and socially withdrawn. It is also used to decrease symptoms such as depression, guilt and anxiety associated with schizophrenia.
- Behavioural disturbances in patients with mental illness, who have symptoms of aggressiveness and activity disturbances.
- Conduct and other disruptive behaviour disorders in children (5-12 years) who are intellectually disabled or children with mental illness in whom destructive behaviour occurs.

3. BEFORE YOU TAKE AUROPERDAL

Do not take AUROPERDAL:

- If you are hypersensitive (allergic) to risperidone or any of the other ingredients of **AUROPERDAL**.
- If you are pregnant or lactating.
- Not for children under the age of 5 years.

Take special care with AUROPERDAL:

Tell your doctor if you have or have ever had any medical conditions, especially the following:

• heart or blood vessel problems, including high and low blood pressure.

Low blood pressure can result from using **AUROPERDAL** together with medications to treat high blood pressure. So, if you need to use both **AUROPERDAL** and medications to reduce blood pressure, consult your doctor.

AUROPERDAL should be used with caution, and only after consultation with your doctor, if you have heart problems, particularly irregular heart rhythm, abnormalities in electrical activity of the heart, or if using medications that can change the heart's electrical activity.

- disease of the blood vessels of the brain including stroke
- dehydration
- kidney or liver problems
- Parkinson's disease
- dementia or Lewy body dementia
- epilepsy, seizures
- low blood potassium levels (hypokalaemia)

- low blood sugar
- breast cancer
- disease of the pituitary gland
- diabetes
- Tardive dyskinesia (a reaction to some medicines with uncontrollable twitching or jerking movements of the arms and legs)
- Neuroleptic Malignant Syndrome (a serious reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions).

Driving and using machinery:

AUROPERDAL may make you drowsy. Do not drive or use machinery until you know how **AUROPERDAL** affects you.

Pregnancy and Breast-feeding:

Do not use **AUROPERDAL** without telling your doctor if you are pregnant, think you may be pregnant, or are planning a pregnancy. The safety of this medication in pregnant women has not been established.

Do not use **AUROPERDAL** of you are breast-feeding. This is because small amounts may pass into the mother's milk.

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.

Taking other medicines with AUROPERDAL:

Do not drink alcohol while taking **AUROPERDAL** tablets **AUROPERDAL** can increase the effects of alcohol and other medicines. This can slow your reactions.

Tell your doctor if you are also taking any sleeping tablets, tranquillisers, antihistamines or any strong painkillers. Also tell your doctor if you are taking medicines for depression, panic disorder, anxiety or obsessive-compulsive disorder such as venlafaxine, paroxetine or fluoxetine. Paroxetine and fluoxetine may increase the level of **AUROPERDAL** in your blood.

Also tell your doctor if you are taking medicines for:

Parkinson's disease or a tremor such as levodopa.

Diuretics, especially furosemide. It is possible that the combination of **AUROPERDAL** and furosemide may be harmful. There is an increased risk of side effects or death in elderly people if furosemide is also taken with **AUROPERDAL**.

Other medicines for your heart or blood pressure such as beta blockers.

Medicines to treat mental illness or psychotic conditions such as lithium.

Carbamazepine, a medicine mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face) may decrease the level of **AUROPERDAL** in your blood.

Medicines used to treat ulcers and reflux such as cimetidine and ranitidine.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of AUROPERDAL with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

3. HOW TO TAKE AUROPERDAL

Always take **AUROPERDAL** 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 **AUROPERDAL** is too strong or too weak, talk to your doctor or pharmacist.

Take **AUROPERDAL** only as directed by your doctor.

Your doctor will tell you how much medicine to take and for how long. This will depend on your condition and varies from person to person. If you have liver or kidney problems your doctor will give you a lower dose.

- For the treatment of schizophrenia:

The adult dose is usually taken once or twice a day.

When you start taking **AUROPERDAL,** you will normally take the following amount:

- 2 mg on the first day.
- 4 mg on the second day.

The number of **AUROPERDAL** tablets you take will then be maintained or adjusted until your doctor finds the dose that suits you best. This is usually between 4 mg and 8 mg a day.

If you are elderly, your doctor will start you on a lower dose.

❖ For the treatment of behavioural problems in adults with dementia:

- The usual dose you start with is 0,25 mg twice a day.
- Your doctor will adjust this dose if necessary.
- Most patients feel better with a dose of 0,5 mg twice a day.

❖ For the treatment of behaviour problems in children aged 5 to 12 years:

The dose for children is based on their body weight, and will be determined by your doctor.

If you take more AUROPERDAL than you should:

In case of overdose 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 heart beats.

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

If you forget to take AUROPERDAL:

Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

AUROPERDAL can have side-effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking **AUROPERDAL**

You may need medical treatment if you get some of the side effects.

Taking it for the first time. At the start of treatment you may have a fall in blood pressure making you feel dizzy on standing up, or your heart may beat faster. These should go away after a few days. Tell your doctor if they continue or worry you.

If any of the following happen, stop taking AUROPERDAL and tell your doctor immediately or go to Emergency at your nearest hospital:

- rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body. If you have them, you may have had a serious allergic reaction to **AUROPERDAL**.
- sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech (these are called mini-strokes)
- in elderly patients with dementia, occurrence of following even for a short period time: sudden weakness or numbness of the face, arms or legs, especially on one side, instances of slurred speech and stroke These are very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

heart or blood pressure problems such as:

- fall in blood pressure, particularly on standing. This will be apparent to you as light-headedness or dizziness that passes after a few seconds or after sitting down again
- faster heart rate, slowed heart rate, heart beat irregularities

body temperature changes such as:

- fever
- abnormally high body temperature

These may be serious side effects of **AUROPERDAL**. You may need urgent medical attention.

Serious side effects are uncommon.

Tell your doctor if you notice any of the following and they worry you:

difficulty thinking or working because of:

• sleeplessness

• headache

• trembling

• drowsiness, tiredness, difficulty in concentrating

behavioural changes such as:

• agitation

• anxiety

joint or movement changes such as:

• muscle stiffness

• restlessness in the legs

other changes such as:

• weight gain

• indigestion, nausea, abdominal pain, constipation

• excessive thirst

• frequent urination

• unusual secretion of breast milk

• breast swelling

• missed or irregular menstrual periods

• involuntary movements of the tongue, face, mouth, jaws, arms, legs or trunk

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF AUROPERDAL

Store all medicines out of the reach and sight of children.

Store at or below 30 °C. Do not remove from the carton until required for use.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF AUROPERDAL

Tablets are packed in clear 250 micron PVC film laminated with 25 micron PE, coated with 90 gsm PVdC and 25 micron Printed Aluminium foil. Each blister contains 10 tablets.

Pack Size for **AUROPERDAL 0.5 mg**: Each carton contains 2 blisters of 10 tablets each.

Pack Size for **AUROPERDAL 1 mg, AUROPERDAL 2 mg, AUROPERDAL 3 mg and AUROPERDAL 4 mg:**

Each carton contains 3 blisters of 10 tablets each.

8. IDENTIFICATION OF AUROPERDAL

AUROPERDAL 0.5 mg: Green coloured film coated biconvex caplets, debossed on one side with “A” and on the other side with “50”. Score line between “5” and “0”.

AUROPERDAL 1 mg: White coloured film coated biconvex caplets, debossed on one side with “A” and on the other side with “51”. Score line between “5” and “1”.

AUROPERDAL 2 mg: Light orange coloured film coated biconvex caplets, debossed on one side with “A” and on the other side with “52”. Score line between “5” and ‘2”.

AUROPERDAL 3 mg: Yellow coloured film coated biconvex caplets, debossed on one side with “A” and on the other side with “53”. Score line between “5” and “3”.

AUROPERDAL 4 mg: Green coloured film coated biconvex caplets, debossed on one side with “A” and on the other side with “54”. Score line between “5” and “4”.

9. REGISTRATION NUMBER/REFERENCE NUMBER

AUROPERDAL 0.5 mg: 42/2.6.5/0330

AUROPERDAL 1 mg: 42/2.6.5/0331

AUROPERDAL 2 mg: 42/2.6.5/0332

AUROPERDAL 3 mg: 42/2.6.5/0333

AUROPERDAL 4 mg: 42/2.6.5/0334

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

Date of registration:

05 August 2011

Date of revision:

06 December 2022