

RESPIDON TABLET

Risperidone (1mg, 2mg, 3mg)

What is in this leaflet

1. What is Risperidon used for
2. How Risperidon works
3. Before you use Risperidon
4. How to use Risperidon
5. While you are using it
6. Side effects
7. Storage and Disposal of Risperidon
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Risperidon is used for

It is used to treat psychotic conditions which affect the way you think, feel and/or act. These are associated with symptoms such as confusion, hallucinations (e.g. hearing, seeing or sensing things which are not there), delusions, unusual suspiciousness (paranoia), emotional and social withdrawal.

People with the above mentioned conditions also feel depressed, guilty, anxious or tense. For both sudden and long-lasting disorders Risperidone may be used.

Ask your doctor if you are still unsure why you have been prescribed this medicine.

How Risperidon works

Risperidone rebalances of certain natural substances in the brain (such as dopamine and serotonin) to improve thinking, mood, and behaviour.

Before you use Risperidon

- When you must not use it

Do not take Risperidon if you:

- Are allergic to Risperidone or any of the ingredients. These allergic reactions include rash, itching, swollen face or lips, or shortness of breath.
- Have bone-marrow depression.
- Have phaeochromocytoma (tumor of the adrenal glands).

It is not to be used for individual in coma that is caused by the medicine Central Nervous System depressants.

Pregnancy and lactation

Do not take Risperidon if you are pregnant, trying to get pregnant or think you may be pregnant. Only take Risperidon during pregnancy if the benefit justifies the potential risk to the baby.

Do not take Risperidon if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Before taking Risperidone tablets tell your doctor or pharmacist if you:

- Are having an eye surgery.
- Have orthostatic hypotension (low blood pressure that happens when you stand up from sitting or lying down).
- Have heart or blood vessel disease, liver or kidney disease, Parkinson's disease (progressive disorder that affects movement), epilepsy or dementia (loss of memory and thinking ability).
- Have had a stroke or temporary reduction in blood flow to the brain (transient ischemic attack).
- Have diabetes, high blood pressure and smoking habit.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop, especially:

- Medicines used to treat Parkinson's symptoms such as medicine consist levodopa and other dopamine agonists. Risperidone may affect way of these medicines work.
- Antipsychotics such as phenothiazines and haloperidol.
- Tricyclic antidepressants and some beta blockers (such as fluoxetine).
- Valproate and carbamazepine used for the treatment of epilepsy.

Alcohol should be avoided whilst taking this medicine because it may causes drowsiness feeling.

How to use Risperidon

- How much to use

Follow the instructions of your doctor or pharmacist carefully. It may differ from the information in this leaflet. If you do not understand the instructions

on your medicine label, please consult your doctor or pharmacist.

The usual dosages are listed below. If you have been prescribed a dose that is different from that below you should discuss it with your doctor, if you haven't already done so.

For adults and adolescents 15 years and above with conditions that affect the way they think, feel or act:

The usual dose at the start of treatment is 2 mg once daily, and dose should be gradually increased at the second day 4mg daily.

However your doctor may decide to increase the dose. The dosage will then be set in between 4 and 6mg per day as per individual need or response. In some people, daily dose of 4mg may lead to good effect.

Your treatment should be monitored and changed depending on need and response.

If you have a liver or kidney disorder or are elderly, you should take half the above doses. Consult your doctor that how may tablets you need to take.

- When to use it

Each dose should be swallowed with a drink of water, with or without food.

Do not chew or crush the tablets. To help you to remember to take your medicine regularly it is recommended that you try and take each dose at the same time each day.

- How long to use it

Continue taking Risperidon for as long as your doctor recommends

- If you forget to use it

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there

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are no signs of discomfort or poisoning. You may need urgent medical attention.

Signs and symptoms of overdose:

- Drowsiness and sedation.
- Fast heart rate.
- Low blood pressure.
- Extrapyrimal symptoms (such as abnormal, uncontrolled, involuntary movement).

While you are using it

- Things you must do

- Tell all the doctors, dentists and pharmacists that are treating you that you are taking Respidon.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not take any new medicines without consulting your doctor.
- Do not give Respidon to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Risperidone daily dose should not be increased more than a total of 16 mg.

Risperidone should not be used in children below 15 years of age.

As you feel better, do not stop your treatment continue the Risperidone treatment as per the doctor's instructions.

If you have been taking a high dose of Risperidone and you want to stop Risperidone treatment, you should do so gradually, unless your doctor has told you otherwise. If you stop Risperidone treatment suddenly it may cause effects such as feeling sick, vomiting, sweating, sleeplessness, muscle stiffness or jerky movements, or your original medical problem may come back. Always follow your doctor's instructions carefully.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Below are the reported side effects of Respidon:

- Headache, sleeplessness, anxiety or agitation.
- Risperidone treatment may cause sleepiness, tiredness, difficulty in concentrating, blurred vision, constipation, indigestion, feeling or being sick (nausea or vomiting), stomach ache, sexual dysfunction, bedwetting, runny or blocked nose, yellowing of the eyes and skin, local skin rash or swelling, or other allergic reactions such as itching, swollen face or lips, or shortness of breath.
- Weight gain may also occur.
- Strokes or transient ischemic attacks may also occur. Seek medical attention if you feel sudden weakness or numbness of the face, arms or legs, especially on one side and slurred speech.
- High blood sugar has been reported. Consult with your doctor if you experience excessive thirst or urination.
- Symptoms like trembling, pronounced muscle stiffness or spasm, slowness of movement, excess saliva or restlessness can occur.
- Use of Risperidone in women may suffer from milk secretion, an absence of their monthly period or changes in the regularity of their periods. Men may experience breast swelling. Consult your doctor if it happens.
- Changes in the blood cell count have been reported.
- You may feel dizziness due to fall in blood pressure in the early stages of the treatment. This will disappear automatically.
- Risperidone may cause a desire to drink large amounts of water, marked changes in body temperature or uncontrollable movements.
- Risperidone might cause fever, faster breathing, and reduced consciousness. If this occurs, stop taking the tablets and contact a doctor at once.

- Continuous erection of penis.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Tell your doctor if you get any side effect that bothers you or that does not go away.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects (ConSERF) or Vaccine (AEFI)).

Storage and Disposal of Respidon

- Storage

- Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

RESPIDON 1MG TABLET:

White, biconvex, oblong film coated tablets with break line on one side.

RESPIDON 2MG TABLET:

Pale orange, biconvex, oblong film coated tablets with break line on one side.

RESPIDON 3MG TABLET:

Light Yellow, biconvex, oblong film coated tablets with break line on one side.

- Ingredients

Active ingredient:

- Risperidone.

Inactive ingredients:

- Lactose monohydrate.
- Maize starch.
- Cellulose microcrystalline.
- Sodium lauryl sulphate.
- Silica colloidal anhydrous.
- Magnesium Stearate.
- Hypromellose.
- Propylene glycol.

RESPIDON TABLET

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- Titanium dioxide.
- Purified talc.
- Orange yellow S Lake Colour (Risperidone 2mg only)
- Quinoline yellow (Risperidone 3mg only)

- *MAL number(s)*:

RESPIDON 1MG TABLET:

MAL07050016AZ

RESPIDON 2MG TABLET:

MAL07050018AZ

RESPIDON 3MG TABLET:

MAL07050019AZ

Manufacturer

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Product Registration Holder

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