

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Risperidone 0.5mg, 1mg, 2mg, 3mg, 4mg and 6mg film-coated Tablets**

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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## 1. What Risperidone film-coated Tablets are and what they are used for

Risperidone is a type of medicine called an antipsychotic, which helps to improve the way you think, feel and/or act.

Risperidone film-coated Tablets are used to treat:

- Sudden and long lasting schizophrenic conditions and other psychotic conditions; symptoms include hallucinations, delusions, thought disturbances, hostility, suspiciousness, blunted affect, emotional and social withdrawal and poverty of speech
- Symptoms such as depression, feelings of guilt and anxiety, associated with schizophrenia
- Mania symptoms in patients with bipolar disorder

Risperidone may also be used long term to prevent these symptoms returning.

## 2. Before you take Risperidone film-coated Tablets

**Do not take Risperidone film-coated Tablets if you are:**

- allergic to any of the ingredients of these tablets, listed in Section 6 or Section 2 (Important information about some of the ingredients of Risperidone film-coated tablets).

**Take special care if you:**

- If you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- are sugar intolerant
- have heart or blood vessel disease, high blood pressure, Parkinson's disease, epilepsy, diabetes, kidney or liver problems, or you are a current smoker
- are an elderly patient (over 65 years) with dementia taking diuretics, such as furosemide, as you may become dehydrated

Risperidone is **not** recommended for the treatment of behavioural symptoms of dementia because it may cause sudden weakness or numbness of the face, arms or legs, slurred speech or problems with your vision.

**Taking other medicines**

You should make sure you have told your doctor or pharmacist about any other medicines that you are taking, including any you have bought without a prescription. If you answer yes to any of the following questions, talk to your doctor before taking this medicine:

- fluoxetine, paroxetine, sertraline (for your nerves),
- carbamazepine (for epilepsy)
- anti-histamines (for allergies)
- beta-blockers such as atenolol and propranolol (for irregular heartbeat)
- anti-diuretics, such as furosemide (for water retention)
- for prevention of malaria

**Taking Risperidone film-coated Tablets with food and drink**

Risperidone film-coated tablets can be taken before a meal or on an empty stomach. You should be careful how much alcohol you drink, because the combined effect of alcohol and your medicine might make you feel drowsy.

**Pregnancy and breast-feeding**

You should not take Risperidone film-coated Tablets if you are planning to become pregnant, if you are pregnant or if you are breastfeeding, unless advised by your doctor. The following symptoms may occur in newborn babies, of mothers that have used Risperidone film-coated Tablets 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.

**Driving and using machines**

These tablets may interfere with activities requiring mental alertness. Take care when taking these tablets, as your ability to drive or operate machinery may be affected.

**Important Information about some of the ingredients of Risperidone film-coated Tablets**

This product contains lactose. If you have been told by your doctor that you have intolerance to some sugars, talk to your doctor before taking this medicine. The 2mg tablets also contains E110, which may cause an allergic reaction.

## 3. How to take Risperidone film-coated Tablets

Always take Risperidone film-coated Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You may take your tablets at any time of the day, ideally before a meal or on an empty stomach. Your doctor will tell you how many tablets to take, and when to take them. You may divide your dose into one or two doses daily. Tablets can easily be broken in half to aid swallowing.

**Treatment of schizophrenic conditions**

Adults:

The initial dose on day 1 is 2mg either as a single dose or two separate doses. On the second day the dosage may be increased to 4mg. Most patients typically benefit from a daily dose of 4 to 6mg. The maximum daily dose is 16mg.

The elderly:

The initial dose is 0.5mg twice a day, and the usual dose is 1 to 2 mg daily.

Children:

Not recommended in children under 15 years of age.

**Treatment of mania**

Adults:

Initially 2mg daily, if required the dosage may be increased daily by 1mg up to a maximum of 6mg.

The elderly:

The initial dose is 0.5mg twice a day, and the usual dose is 1 to 2mg daily.

Children:

Not recommended in children under 15 years of age

## Patients with kidney or liver problems

The initial dose is 0.5mg twice a day, and the usual dose is 1 to 2mg daily. Risperidone should be used cautiously in this group of patients.

## If you forget to take Risperidone film-coated Tablets

If you forget to take your tablets, take them as soon as you remember unless it is almost time for the next dose. Do not take a double dose to make up for a forgotten individual dose.

## If you take more Risperidone film-coated Tablets than you should

If you take more than the recommended number of tablets, contact your doctor or pharmacist immediately. Take this leaflet and the pack of Risperidone film-coated Tablets along with you, if you can.

## If you stop taking Risperidone film-coated Tablets

Do not stop taking Risperidone film-coated tablets even if you start feeling better. Continue taking Risperidone film-coated tablets as long as your doctor has advised you. The withdrawal of Risperidone may cause nausea, vomiting, sweating, inability to sleep, and a return of your symptoms (see section 1). If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, Risperidone film-coated Tablets may cause side effects, although not everybody gets them. Many effects are usually mild and go away when you stop taking this medicine.

Side effects with Risperidone film-coated tablets may include:

### Common side effects (less than 1 in 10 people but no more than 1 in 100 people):

- inability to sleep, feelings of agitation or anxiety and headaches.

### Less common side effects (less than 1 in 100 people but more than 1 in 1,000 people):

- sleepy, tiredness, dizziness, low blood pressure, fast pulse, poor concentration, constipation, stomach upset, nausea or vomiting, abdominal pain, blurred vision, male sexual problems, urinary incontinence, sore or blocked nose, rash and other allergic reactions.
- tremor, rigidity, excess salivation, slow movements, restlessness, weight gain, irregular periods, male breast enlargement, and abnormal muscle tone, milk production, and blood chemistry,
- stroke or transient ischaemic attacks (temporary reduction in the blood supply to the brain); if you experience sudden weakness or numbness of the face, arms or legs, especially on one side, or instances of slurred speech, **you must seek immediate medical attention**

### Rare side effects (affecting less than 1 in 1000 people but no more than 1 in 10,000 people):

Excessive thirst and water intoxication; involuntary twitching tongue and facial movement, poor control of body temperature, seizures,

### Very rare side effects (affecting less than 1 in 10,000 people but no more than 1 in 100,000 people):

High blood sugar levels and loss of control in diabetics; angioedema and benign growths. Sedation, which is usually mild and short lived, has mainly been reported in children and adolescents.

### Frequency unknown:

Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through the blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.

If you suffer from any of these side effects, or if you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## 5. How to store your Risperidone film-coated Tablets

Keep out of the reach and sight of children. Do not store above 25°C and keep the tablets in their original package

Do not use Risperidone film-coated Tablets after the expiry date which is stated on the carton after 'Expiry:' The expiry date refers to the last day of that month.

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.

## 6. Further information

### What Risperidone film-coated Tablets contain

The active substance is Risperidone.

The other ingredients in the tablet are: lactose monohydrate (Section 2 Important information about some of the ingredients of Risperidone film-coated tablets), starch pregelatinised, cellulose microcrystalline, sodium laurilsulfate, silica colloidal anhydrous, talc, magnesium stearate, hypromellose, titanium dioxide (E171) and macrogol 400. Tablet coatings contain:

0.5mg tablet: red and yellow iron oxides (E172), and hydroxypropyl methylcellulose.

2mg tablet: sunset yellow (E110) and quinoline yellow (E104)

3mg tablet: quinoline yellow (E104)

4mg tablet: quinoline yellow (E104) and indigo carmine (E132).

6mg tablet: hypromellose and FD&C Yellow #5/tartrazine Aluminum Lake (E102).

### What Risperidone film-coated Tablets look like and contents of the pack

Each brown tablet contains equivalent to 0.5mg of Risperidone.

Each white tablet contains equivalent to 1mg of Risperidone.

Each orange tablet contains equivalent to 2mg of Risperidone.

Each yellow tablet contains equivalent to 3mg of Risperidone.

Each green tablet contains equivalent to 4mg of Risperidone.

Each yellow tablet contains equivalent to 6mg of Risperidone.

Your Risperidone Tablets are supplied in boxes containing 20 or 50 tablets for 0.5mg, 20, 28, 50 or 60 tablets for 1mg, 2mg, 3mg and 4mg Risperidone. The 6mg strength is packaged in boxes of 28, 50 or 60 tablets.

Marketing Authorisation Holder and Manufacturer: Dr. Reddy's Laboratories (UK) Ltd., 6 Riverview Road, Beverley, HU17 0LD, UK

Risperidone 0.5mg Tablets	PL 08553/0259	Risperidone 3mg Tablets	PL 08553/0257
Risperidone 1mg Tablets	PL 08553/0255	Risperidone 4mg Tablets	PL 08553/0258
Risperidone 2mg Tablets	PL 08553/0256	Risperidone 6mg Tablets	PL 08553/0260

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