PACKAGE LEAFLET: INFORMATION FOR THE USER

Rispefar 1 mg, 2 mg, 3 mg, 4 mg, 6 mg and 8 mg film-coated tablets
Risperidone

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.

In this leaflet:

1. WHAT RISPEFAR IS AND WHAT IT IS USED FOR

Rispefar is an antipsychotic drug. Psychosis disturbs the brain function in such a way that thoughts, feelings and behavior are affected. One may feel followed, hear voices, have a hard time concentrating and feel alienated. Rispefar inhibits the symptoms of psychosis in such a way that they become milder or disappear.

Rispefar is used for treatment of:
- Schizophrenia; acute and chronic schizophrenic psychoses.
- Certain diseases with manic phases, characterized by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility, or poor judgement, including disruptive or aggressive behaviors.
- Backward or mentally retarded children, adolescents and adults with severe destructive behavior (e.g. aggression, impulsive behavior and self damaging behavior), when non medical psychosocial therapy has not had adequate effect.

The doctor may have prescribed other use. Always follow your doctor's prescription.

2. BEFORE YOU TAKE RISPEFAR

Do not take Rispefar
- if you are allergic (hypersensitive) to risperidone or any of the other ingredients of Rispefar.

Take special care with Rispefar
Get information from your doctor before you take Rispefar, if you have or have had any of the following diseases, because it may be necessary to adjust your dose:

- Cardiovascular disorder
- Low blood pressure with dizziness (orthostatic hypotension)

- Kidney or liver disease
- Hearts or blood vessel disease
- Parkinson's disease
- Epilepsy

Elderly persons with dementia, treated with risperidone, have an increased risk of strokes (possibly fatal) and transient decreased blood flow to the brain (transient ischemic attack). Symptoms of this are sudden paralysis in the face, legs or arms (only in one side of the body), slurred speech and disturbances of vision. If such symptoms occur, a doctor should be contacted immediately.

You should avoid eating excessively, because there is an increased risk of weight gain.

Rispefar contains lactose monohydrate. Contact your doctor before taking this medicine if your doctor has told you that you are intolerant to certain types of sugar.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, natural supplements and strong vitamins and minerals.

It is especially important that you tell your doctor if you are taking:

- other drugs that act on the central nervous system (e.g. other antipsychotic drugs), because there is a greater risk of side effects.
- dopamine stimulating drugs e.g. levodopa, bromocriptin and pergolide (for Parkinson's disease) because risperidone may antagonize the effect of these medical products.
- liver enzyme increasing drugs e.g. carbamazepine (for epilepsy) because these medical products may decrease the plasma level of risperidone and as a result the antipsychotic effect of risperidone may be decreased.
- centrally functioning drugs e.g. sleeping pills and certain pain killers, because these medical products may increase the plasma concentration of risperidone but they have no effect on the antipsychotic effect of risperidone.
- certain drugs for depression e.g. paroxetine and fluoxetine, because these medical products may increase the plasma concentration of risperidone but they have only little effect on the antipsychotic effect.
- certain beta-blockers (for heart and blood pressure), because these medical products may increase the plasma concentration of risperidone but they have no effect on the antipsychotic effect of risperidone.
- furosemide (diuretic), because patients treated with furosemide plus risperidone have a higher incidence of mortality.
- drugs used to correct heart rhythm disorders, certain antibiotics (moxifloxacin and erythromycin), methadone, anti-malaria drugs (mefloquine), lithium (used to treat manic depression) or cisapride (used in intestinal disease). Concomitant use with certain water tablets (thiazide diuretics), because these can reduce levels of potassium in the blood and thereby increase the risk for heart rhythm disorders.

Contact your doctor. A dose adjustment may be necessary.

Taking Rispefar with food and drink
You can take Rispefar with food and drink. Rispefar may enhance the effect of alcohol. Therefore, you should not drink alcohol when taking Rispefar.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy:
Do not take Rispefar, if you are pregnant.

Breast-feeding:
If you are breast-feeding, do not take Rispefar.

Driving and using machines
Use of Rispefar may cause somnolence to some extent. You must be aware of this, if you are to drive or use machines.

Important information about some of the ingredients of Rispefar
Rispefar contains lactose monohydrate. Please refer to "Take special care with Rispefar". 2 mg tablets contain the color Sunset Yellow (E110), which may cause allergic reactions.

3. HOW TO TAKE RISPEFAR

Always take risperidone exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dosing is as follows:

Schizophrenia; acute and chronic schizophrenic psychoses:

Adults:
Rispefar may be administered 1 or 2 times daily.
The usual initial dose is 2 mg daily. The dose is increased over days according to your doctor's instructions to a usual maintenance dose of 4-6 mg daily divided in 1 or 2 doses.

Elderly:
It is necessary to adjust the dose. Follow the doctor's instructions.

Children:
There is no experience in treating children under the age of 15 years.

Certain diseases with manic phases, characterized by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility, or poor judgement, including disruptive or aggressive behaviors:

Adults
Rispefar may be administered once daily.
The usual initial dose is 2 mg daily. Rispefar should be administered with an initial dose of 2 mg. This dose may be increased by 1 mg at a time with at least 24 hours in between. For most patients the optimal maintenance dose will be 2-6 mg/day.

Elderly
It is necessary to adjust the dose. Follow the doctor's instructions.

Children
There is no experience in treating children and adolescents under the age of 18 years.

Backward or mentally retarded children, adolescents and adults with severe destructive behavior (e.g. aggression, impulsive behavior and self damaging behavior), when non medical psycho-social therapy has not had adequate effect:

Adults (body weight > 50 kg)
An initial dose of 0.5 mg once daily is recommended. This dose may be individually adjusted in increments of 0.5 mg once daily, every other day. The optimal dose for most patients is 1 mg once daily.

Children and adolescents (body weight < 50 kg)
An initial dose of 0.25 mg once daily is recommended. This dose may be individually adjusted in increments of 0.25 mg once daily, every other day. The optimal dose for most patients is 0.5 mg once daily. There is no experience in treating children under the age of 5 years.

Kidney or liver disease:
It is necessary to decrease the dose. Your doctor's prescription must be followed.

Always follow your doctor's prescription. Your dose is individual.

If you take more Rispefar than you should
Contact a doctor, the emergency room or pharmacy if you have taken more Rispefar than noted in this leaflet or prescribed by your doctor.

Symptoms of overdose may be somnolence, sleepiness, pounding heart, low blood pressure and trembling and rigid muscles.

If you forget to take Rispefar
Do not take a double dose to make up for a forgotten dose, but take the next dose as usual.

If you stop taking Rispefar
Change or discontinuation of treatment should only be performed with consent of your doctor. Treatment with Rispefar should usually be discontinued gradually.
Withdrawal symptoms are: nausea, vomiting, sweating, insomnia, involuntary movement disorders (such as akathisia, dystonia and dyskinesia).

4. POSSIBLE SIDE EFFECTS

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

Severe side effects:

Uncommon side effects (occur in between 1 and 10 of 1.000 treated):
Stroke (possibly fatal) and transient decreased blood flow to the brain (transient ischemic attack). Symptoms of this are sudden paralysis in the face, legs or arms (only in one side of the body), slurred speech and disturbances of vision. (please refer to"Take special care with Rispefar").

Condition with muscle rigidity, fever and decreased consciousness (malignant neuroleptic syndrome)

Rare (occur in less than 1 in 1000 treated and more than 1 in 10 000 treated)*:*
Effects on heart rhythm and irregular heart rhythm and associated ECG changes. Cardiac arrest.

If above mentioned symptoms occur, a doctor must be contacted immediately.

Non-severe side effects:

Common side effects (occur in between 1 and 10 of 100 treated): Disturbed sleep. Excitement. Anxiety. Headache. Sedation has been reported more often in children and adolescents, than in adults. Genrally sedation is light and temporary.

Uncommon side effects (occur in between 1 and 10 of 1.000 treated):
Fatigue, dizziness, difficulty in concentrating, constipation, nausea, vomiting, stomachache, blurred vision, changes in sexual ability, involuntary urination (incontinence), changed menstrual cycle, breast milk production, increased breast glands in men, runny nose, rashes or other allergic reactions. Muscle rigidity, decreased ability to move, trembling. Convulsions, involentary movements of the tongue (tardive dyskinesia). Pounding heart and dizziness during change from sitting or lying to upright positions, low blood pressure (hypotension). Changed composition of the blood and increased liver enzymes. Weight increase, retained fluid (edema), disturbances in body temperature.

In rare or very rare cases other non- severe side effects than those listed here may occur. If you want information on these, contact your doctor or pharmacy.

4. HOW TO STORE RISPEFAR

Keep out of the reach and sight of children.

Store below 25^0C.

Do not use Rispefar after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not use Rispefar if you notice visible changes in the appearance of the medicinal product.

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 Rispefar contains

- The active substance is risperidone
- The other ingredients are:

Tablet core: lactose monohydrate, maize starch, sodium laurilsulphate, cellulose microcrystalline, hypromellose, silica colloidal anhydrous, magnesium stearate.

Film-coating: hypromellose, titanium dioxide (E171), propylene glycol, talc
Additional colors: 1 mg: opadry white: titanium dioxide (E171), 2 mg: opadry orange: sunset yellow FCF aluminium lake (E110), 3 mg: opadry yellow: quinoline yellow aluminium lake (E104), 4 mg: opadry green: indigo carmine aluminium lake (E132), quinoline yellow aluminium lake (E104), 6 mg: opadry yellow: quinoline yellow aluminium lake (E104), 8 mg: opadry Green: indigo carmine aluminium lake (E132), quinoline yellow aluminium lake (E104).

What Rispefar looks like and contents of the pack

1 mg: White, oblong film-coated tablet 11 x 5.5 mm with scoreline on both sides.
2 mg: Orange, oblong film-coated tablet 11 x 5.5 mm with scoreline on both sides.

3 mg: Yellow, oblong film-coated tablet 11 x 5.5 mm with scoreline on both sides.
4 mg: Green, oblong film-coated tablet 11 x 5.5 mm with scoreline on both sides.
6 mg: Yellow, round, biconvex film coated tablet with a diameter of 8.0 mm with scoreline on one side.
8 mg: Green, round, biconvex film coated tablet with a diameter of 8.0 mm with scoreline on one side.

Tablets are provided in PVC/PE/PVDC/Aluminium blisters.

1mg, 2mg, 3mg, 4mg, 6mg: Contents of container: 20 or 60 film-coated tablets (in 10 tablets blister packs)
8mg: Contents of container: 20 or 50 film-coated tablets (in 10 tablets blister packs)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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