

Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 08/2020

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name:RISPERIDONE TABLETS 3「OHARA」

Active ingredient:Risperidone

Dosage form:white tablet, diameter: 8.1 mm, thickness : 3.5 mm

Print on wrapping:リスぺリドン 3「オーハラ」,3 mg,リスぺリドン, Risperidone 3「OHARA」



Effects of this medicine

This medicine controls actions of dopamine and serotonin, which work on the central nervous system, to relieve symptoms such as anxiety or stress. It helps reduce an imbalance in mental status and improve negative symptoms such as lack of drive or interest. It is usually used for treatment of schizophrenia.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.
If you are in a coma, debility with dehydration or malnutrition.
If you have or are suspected to have cardiovascular disease or hypotension.
If you have: Parkinson's disease, dementia with Lewy bodies, convulsive disease such as epilepsy or history of this disease, suicidal thought or history of suicide attempt, liver/kidney disorders, diabetes, past history or family history of diabetes disease, hyperglycemia or obesity.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- In general, for adults, start taking 1 mg of the active ingredient at a time, twice a day and then gradually increase the dosage. The dosage is maintained on 1 to 3 mg at a time, twice a day. The dosage may be adjusted according to the age or symptoms. However, the daily dosage is up to 12 mg.
This preparation contains 3 mg of the active ingredient in a tablet. Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. If you have only 5 hours or less until the next dose, skip the missed dose and continue your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- This medicine may cause drowsiness, lack of attention, concentration and reflex action ability. Avoid operating machinery with potential risk such as driving a car.
- Drinking alcohol may intensify the medicine's effect. Avoid drinking during medication.
- Be sure to tell your doctor that you take this medicine if you are scheduled for cataract surgery. This medicine may cause eye-complication intra or post-surgery.
- Always pay attention to your diet or body weight to improve your lifestyle habit.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include increased body weight, bulimia, dizziness, akathisia (a state of motor restlessness), insomnia, trembling body, constipation, restless feeling, drowsiness, excess saliva, anxiety, malaise and muscular rigidity. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- severe muscular rigidity, difficulty in swallowing, rapid fever [neuroleptic malignant syndrome]
- protruding or retracting the lips, putting out the tongue [[tardive dyskinesia]
- pain of the limb muscle, stiffness, numbness [rhabdomyolysis]
- thirst, excessive intake of water, excessive secretion of urine [hyperglycemia, diabetic ketoacidosis, diabetic coma]
- respiratory distress, chest pain, edema [pulmonary embolism, deep vein thrombosis]]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of the reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. If you dispose of unused medicines, seek advice of your pharmacist or medical institution about proper disposal of them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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