

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

Internal

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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:Permax Tablets 250mcg

Active ingredient:Pergolide mesilate

Dosage form:light green tablet, major axis: 11.7 mm, minor axis: 6.4 mm, thickness: 3.8 mm

Imprint or print on wrapping:KH121, ペルマックス 250 μg, PERMAX 250



Effects of this medicine

This medicine stimulates receptors (D₁ and D₂) for neurotransmitters (dopamine) in the brain, and improves symptoms such as trembling hands, muscle stiffness and slow movement.

It is usually used in the treatment of Parkinson's disease.

The following patients may need to be careful when 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 or foods.
- If you have been diagnosed to have cardiac valve disease by echocardiography or a history of it.
- 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, take 50 mcg of the active ingredient at a time, once a day, immediately after supper for 2 days. The dosage will be increased by 50 mcg per day every 2 or 3 days, and then take 150 mcg a day at the end of the first week of administration. In the second week, start with taking 300 mcg a day and the dosage will be increased by 150 mcg per day every 2 or 3 days, and then take 600 mcg a day at the end of the second week. Patients who are instructed to take 100 mcg a day should take them immediately after breakfast and supper; and who are instructed to take 150 mcg a day should take them immediately after each meal in divided doses. In the third week, start with taking 750 mcg a day and the dosage will be gradually increased with observing the efficacy and safety and the maintenance dose (standard a day dose: 750 to 1,250 mcg) will be determined. Speed of dose increasing may be adjusted according to the symptoms or age. This preparation contains 250 mcg of the active ingredient in a tablet. Strictly follow the instructions.
- If you miss a dose, take a dose as soon as you remember. However, if it is almost time for 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 sudden onset of sleep and somnolence (state close to sleep) without any signs. Do not drive a car, work at heights or engage in dangerous activities.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include anxiety/excitement/feeling irritated, dyskinesia (involuntary movement of limbs and body), dizziness/light headedness, nausea, vomiting, stomach discomfort/heartburn, loss of appetite, hallucination and delusions. 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.

- high fever, stiffness of the body, trembling limbs [neuroleptic malignant syndrome]
- fever, cough, breathing difficulty [interstitial pneumonia]
- chest pain, shortness of breath, breathing difficulty [pleurisy, pleural effusion, pleural fibrosis, pulmonary fibrosis, pericarditis, pericardial exudate, valvular disease of heart]
- back pain, edema of lower limbs, decreased urine output [retroperitoneal fibrosis]
- sudden intolerable drowsiness [sudden onset of sleep]
- feeling as if something that actually does not exist exists, baseless and improbable thoughts, mild confused consciousness [hallucination, delusions, delirium]
- vomiting, difficulties with passing stools or flatulence, abdominal pain [intestinal obstruction]
- decreased consciousness, fainting for a short time and collapsing [consciousness disturbance, syncope]

- general dullness, loss of appetite, yellowing of the skin and the white of eyes [liver dysfunction, jaundice]
- gum bleeding, bruise, prolonged bleeding [thrombocytopenia]

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 do not know how to discard, seek advice of your pharmacy or medical institution. Do not give this medicine to anyone else.
- [To family members] Despite an unfavorable social outcome, the following symptoms may appear: repeated gambling, repeated excessive unplanned shopping, and an abnormal rise in sexual desire and appetite, etc. If any of these symptoms are observed, consult with your doctor.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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