

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

Internal
Revised: 08/2014

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: PAROXETINE TABLETS 5mg 「OHARA」

Active ingredient: Paroxetine hydrochloride hydrate

Dosage form: reddish white tablet, diameter: 5.6 mm, thickness: 2.4 mm

Print on wrapping: パロキセチン 5mg「オーハラ」, OH-57, 5mg, Paroxetine 5mg
「OHARA」



Effects of this medicine

This medicine acts on the neurotransmitters (serotonin) in the brain and shows antidepressive actions and antianxiety actions. It consequently improves symptoms such as depressive mood, anxiety, irritability, loss of motivation, loss of appetite, insomnia, sudden severe anxiety and obsessive thoughts.

It is usually used in the treatment of depression and depressive states, panic disorder, obsessive disorder, social-anxiety disorder and post-traumatic stress disorder.

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 have manic depression, comorbid disorder with high impulsivity, glaucoma, suicidal ideation, a history of suicidal ideation or suicide attempt, predisposition to brain organ disorder or schizophrenia, a history of epilepsy, a tendency to bleed or predisposition to bleeding.
- 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>>
- **For depression and depressive states:** In general, for adults, take 4 to 8 tablets (20 to 40 mg of paroxetine) at a time, once daily, after supper. The administration will be started with taking 2 to 4 tablets (10 to 20 mg of paroxetine) at a time, then the dosage will be increased by 2 tablets (10 mg) per day at an interval of 1 week, however, it may be adjusted according to the symptoms in the range of 8 tablets (40 mg) per day.
For panic disorder: In general, for adults, take 6 tablets (30 mg of paroxetine) at a time, once daily, after supper. The administration will be started with taking 2 tablets (10 mg) at a time, then the dosage will be increased by 2 tablets (10 mg) per day at an interval of 1 week, however, it may be adjusted according to the symptoms in the range of 6 tablets (30 mg) per day.
For obsessive disorder: In general, for adults, take 8 tablets (40 mg of paroxetine) at a time, once daily, after supper. The administration will be started with taking 4 tablets (20 mg) at a time, then the dosage will be increased by 2 tablets (10 mg) per day at an interval of 1 week, however, it may be adjusted according to the symptoms in the range of 10 tablets (50 mg) per day.
For social-anxiety disorder: In general, for adults, take 4 tablets (20 mg of paroxetine) at a time, once a day after dinner. Start taking 2 tablets (10 mg) at a time. As a rule, the dosage is increased by 2 tablets (10 mg) per day at weekly intervals but may be adjusted up to no more than 8 tablets (40 mg) per day according to your symptoms.
For post-traumatic stress disorder: In general, for adults, take 4 tablets (20 mg of paroxetine) at a time, once a day after dinner. Start taking 2 to 4 tablets (10 to 20 mg) at a time. As a rule, the dosage is increased by 2 tablets (10 mg) per day at weekly intervals but may be adjusted up to no more than 8 tablets (40 mg) per day according to your symptoms. This medicine contains 5 mg of paroxetine in 1 tablet. Strictly follow the instructions in any case.
- It usually takes 2 weeks for this medicine to show its therapeutic effects. You should continue to take this medicine after it shows effects.
- 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 follow 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. Sudden withdrawal and dose reduction may cause intolerant symptoms such as dizziness, nausea and sweating. Never stop taking this medicine without instructions.

Precautions while taking this medicine

- This medicine may cause sleepiness and dizziness. Take care in driving a car or operating dangerous machinery.
- Alcohol may intensify the therapeutic effects of this medicine. Avoid drinking alcohol while taking this medicine.
- Take care in taking food that contains *Hypericum perforatum* (St. John's wort) since it may intensify the therapeutic effects of this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea, sleepiness, dry mouth, dizziness, constipation, headache and loss of appetite. 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.

- anxiety, excitation, tremor in limbs [serotonin syndrome]
- muscle stiffness, sweating, sudden fever [malignant syndrome]
- thinking disturbance, seeing things that not existing, decreased consciousness [confusion, hallucination, delirium, convulsion]
- fever higher than 38-degree Centigrade, conjunctival hyperemia and mucosal erosion in lips and eye, circular or elliptic red rash [toxic epidermal necrolysis, oculomucocutaneous syndrome, erythema multiforme]
- general malaise, decreased consciousness, convulsion [syndrome of inappropriate secretion of antidiuretic hormone]
- general malaise, loss of appetite, yellowing in skin and white of eyes [hepatic dysfunction]
- rash, swelling of eyes or around lips, respiratory distress [anaphylaxis]

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. Ask the pharmacist or medical facility how to discard them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

SIE①