

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: Paroxetine Tablets 5mg "SPKK"

Active ingredient: Paroxetine hydrochloride hydrate

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

Print on wrapping: (face) PAROXETINE 5mg, JA TEZ (back) パロキセチン錠 5mg
「SPKK」



Effects of this medicine

This medicine shows antidepressant/anxiolytic effects by acting on the neurotransmitter (serotonin) in the brain, and improves symptoms including gloomy feeling, anxiety, irritation, loss of motivation, loss of appetite, insomnia, acute anxiety, obsession and excessive anxiety/tension in front of others.

It is usually used to treat depression/depressive state, panic disorder, obsessive-compulsive 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-depressive illness, a history of suicidal ideation or suicide attempt, suicidal ideation, predisposition to organic brain disorder or schizophrenia, highly impulsive comorbidities, a past history of epilepsy, glaucoma and a bleeding tendency 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/depressive state: In general, for adults, take 20 to 40 mg of paroxetine at a time, once a day after dinner. Start taking 10 to 20 mg at a time. As a rule, the dosage is increased by 10 mg per day at weekly intervals but may be adjusted up to no more than 40 mg per day according to your symptoms.
For panic disorder: In general, for adults, take 30 mg of paroxetine at a time, once a day after dinner. Start taking 10 mg at a time. As a rule, the dosage is increased by 10 mg per day at weekly intervals but may be adjusted up to no more than 30 mg per day according to your symptoms.
For obsessive-compulsive disorder: In general, for adults, take 40 mg of paroxetine at a time, once a day after dinner. Start taking 20 mg at a time. As a rule, the dosage is increased by 10 mg per day at weekly intervals but may be adjusted up to no more than 50 mg per day according to your symptoms.
For social-anxiety disorder: In general, for adults, take 20 mg of paroxetine at a time, once a day after dinner. Start taking 10 mg at a time. As a rule, the dosage is increased by 10 mg per day at weekly intervals but may be adjusted up to no more than 40 mg per day according to your symptoms.
For post-traumatic stress disorder: In general, for adults, take 20 mg of paroxetine at a time, once a day after dinner. Start taking 10 to 20 mg at a time. As a rule, the dosage is increased by 10 mg per day at weekly intervals but may be adjusted up to no more than 40 mg per day according to your symptoms.
This medicine contains 5 mg of paroxetine in 1 tablet. In any case, strictly follow the instructions.
- It usually takes about 2 weeks for this medicine to show its medicinal effects. You should continue to take this medicine even after it shows the effects.
- If you miss a dose, take the missed dose as soon as possible. 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. Avoid abrupt withdrawal or dose reduction since they may cause intolerant symptoms such as dizziness, nausea and sweating.

Precautions while taking this medicine

- This medicine may cause sleepiness or dizziness. Pay extra attention when operating dangerous machinery, such as driving a car.
- Avoid drinking alcohol while taking this medicine since it may enhance medicinal effects.
- Pay attention when eating foods that contain Saint John's Wort, since it may intensify the medicinal effects.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea, sleepiness, thirst, dizziness, constipation and

headache. 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, shaking of hands [serotonin syndrome]
- acute fever, muscle stiffness, consciousness disorder [malignant syndrome]
- cannot organize thoughts, seeing or hearing things that do not exist, convulsive muscle contraction [confusion, hallucination, delirium, convulsion]
- convulsion, decreased consciousness, headache [syndrome of inappropriate antidiuretic hormone]
- general malaise, yellow discoloration of the white of the eyes, loss of appetite [hepatic dysfunction]

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 pharmacy or medical institution on how to discard them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.