

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: BROTIZOLAM TABLETS 0.25mg 「OHARA」

Active ingredient: Brotizolam

Dosage form: white tablet with split line on one side, diameter: 8.0 mm, thickness: 2.3 mm

Print on wrapping: プロチゾラム錠 0.25mg「オーハラ」、プロチゾラム、0.25mg、OH-54、Brotizolam 0.25mg「OHARA」



Effects of this medicine

This medicine intensifies the effect of GABA (γ -aminobutyric acid), a typical inhibitory transmitter of central nervous system, and suppresses hypothalamic area and cerebral limbic system which control emotion. It consequently blocks unnecessary stimulation from the autonomic nervous system and shows central nervous system depressant effect including hypnotic/sedative/anti-anxiety effect.

It is usually used to treat insomnia and for anesthetic premedication.

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 glaucoma, myasthenia gravis or respiratory disability.
- 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 insomnia: In general, for adults, take 1 tablet (0.25 mg of the active ingredient) at a time right before bedtime.
- For anesthetic premedication: In general, for adults, take 1 tablet (0.25 mg of the active ingredient) before bedtime on the day before surgery, and 2 tablets (0.5 mg) for anesthetic premedication.
The dosage may be adjusted according to your disease, age and symptoms in any case. Strictly follow the instructions.
- If you are going to wake up and briefly work between sleep, do not take this medicine.
- If you miss a dose and have a long time until waking up next morning, you may take the missed dose. 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

- The medicinal effect may continue after the next morning, and may cause sleepiness and decreased attention/concentration/reflex action. Avoid performing dangerous operations such as driving a car.
- Alcohol may intensify the sedative effect of the medicine. Avoid drinking alcohol with this medicine as much as possible.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include residual sleepiness, sleepiness, light headedness, dull headache, dizziness, headache, restlessness, excitation, rash, erythema and malaise. 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.

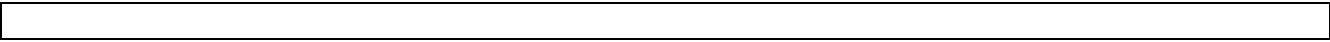
- general malaise, loss of appetite, yellowing of the skin and the whites of the eyes [liver dysfunction, jaundice]
- temporary memory loss after taking the medicine, semi-consciousness [temporary anterograde amnesia, semi-consciousness]

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 light, heat and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /



For further information, talk to your doctor or pharmacist.

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