

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

Internal

Revised: 10/2016

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: Alprazolam Tablets 0.4mg "AMEL"

Active ingredient: Alprazolam

Dosage form: white tablet, diameter: approx. 6.0 mm, thick: approx. 2.1 mm

Print on wrapping: (face) アルプラゾラム 0.4mg「アメル」, アルプラゾラム, 「アメル」, 0.4, KW127
(back) Alprazolam 0.4mg «AMEL», KW127, アルプラゾラム「アメル」, 0.4mg



Effects of this medicine

This medicine suppresses excitement of central nerve and reduces excessive activity of cerebral cortex and cerebral limbic system, relieves anxiety

It is usually used to improve physical sign in psychophysiological disorder (gastroduodenal ulcer, irritable bowel syndrome, autonomic imbalance) and anxiety, stress, depression and sleep disorders.

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 acute narrow angle glaucoma, myasthenia, heart diseases, liver disorder, renal disorder, respiratory diseases, or organic brain disorder.
If you are debilitated.
- 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 1 tablet (0.4 mg of the active ingredient) at a time, three times a day. The dosage should be adjusted according to your age and symptoms. Your doctor may increase your dose if needed; however, the dosage should not be more than 6 tablets (2.4 mg) a day, to be taken in 3 to 4 divided doses. For the elderly, start taking 1 tablet (0.4 mg) at a time, one or two times a day; your doctor may increase your dose if needed, however, the dosage should not be more than 3 tablet (1.2 mg) a day.
Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. 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.

Precautions while taking this medicine

- Drowsiness and lack of concentration/attention/reflex action ability may occur after taking the medicine. Avoid driving a car or operating dangerous machinery.
- Drinking alcohol may intensify the medicine's effects. Refrain from drinking during medication.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include drowsiness, dizziness, lassitude/malaise, dry mouth, rash, itch and photosensitivity reaction (reddened in the body portion that was exposed with light). 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.

- convulsive seizure, mild disturbance of consciousness with false feeling or hallucination, trembling of hands/feet [drug dependency, withdrawal symptom]
- disturbed consciousness and loss of normal thinking ability, impaired mind [stimulative excitement, confusion]
- shallow and rapid breathing, respiratory distress, breathing difficulty [respiratory depression]
- itching, hives, facial reddening/swelling [anaphylaxy]
- general malaise, loss of appetite, yellowing of the skin or whites of the eyes [liver dysfunction, jaundice]

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.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.