

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

Internal

Revised: 11/2015

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:Etizolam Tablets 0.5mg"AMEL"

Active ingredient:Etizolam

Dosage form:white to pale yellowish white tablet, diameter: approx. 6.1 mm, thick:
approx 2.8 mm

Print on wrapping: (face)エチゾラム 0.5mg「アメル」, KW091, エチゾラム, 0.5
(back) Etizolam 0.5mg「AMEL」, 0.5mg, エチゾラム, 0.5mg「アメル」



Effects of this medicine

This medicine acts on benzodiazepine receptors to relieve anxiety and tension. It also relieves muscle tone. It is usually used to improve anxiety/tension/depressive symptom/sleep disorder in neurosis, depression and psychosomatic disease (hypertension, gastroduodenal ulcer). It is also used to improve muscle stiffness in cervical vertebral disease, low back pain and muscle contraction headache.

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 or myasthenia gravis.
- 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 neurosis and depression: In general, for adults, take 2 tablets (1 mg of the active ingredient) at a time, three times a day.
For psychosomatic disease, cervical vertebral disease, low back pain and muscle contraction headache: In general, for adults, take 1 tablet (0.5 mg of the active ingredient) at a time, three times a day.
For sleep disorder: In general, for adults, take 2 to 6 tablets (1 to 3 mg of the active ingredient) at a time, once a day at bedtime.
In any of the above indications, the dosage may be adjusted according to your disease, age and symptom. Strictly follow the instructions.
- If you miss a dose, take the dose as soon as possible. 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 drowsiness and decline of attention/concentration/reflex action ability. Avoid driving a car or operating dangerous machinery.
- Pay attention that drinking alcohol may intensify medicinal effects.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include drowsiness, light headedness, malaise, lassitude, pruritus, hives, rash and erythema. 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.

- unable to control addiction to the medicine, convulsion, insomnia, anxiety [drug dependence]
- general malaise, loss of appetite, yellowing of the skin and whites of the eyes [hepatic dysfunction, jaundice]
- fever (over 37.5 degrees Celsius), muscle stiffness, tremor of limbs [malignant syndrome]
- muscle pain of limbs, numbness, weakness, reddish brown urine [rhabdomyolysis]
- fever, dry cough, respiratory distress [interstitial pneumonia]

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.