

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

Internal

Revised: 07/2022

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: Myslee Tablets 10mg

Active ingredient: Zolpidem tartrate

Dosage form: pale orange tablet with split line on one side, diameter: approx. 8.6 mm, thickness: approx. 3.3 mm

Imprint or print on wrapping: マイスリー10mg, 入眠剤, 就寝直前服用, f631, ゼルピデム (Zolpidem), company mark, アステラス製薬, Myslee 10mg



Effects of this medicine

This medicine enhances the suppressive mechanism of the GABA system by acting on the benzodiazepine receptors in the central nervous system, thus exerting hypnotic and sedative effects.

It is usually used to treat insomnia (excluding insomnia associated with schizophrenia or manic-depressive psychosis).

The following patients may need to be careful when 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 or foods.
If you have: liver disorder, myasthenia gravis, acute angle closure glaucoma, experienced abnormal behavior during sleep when treated with this medicine in the past, decreased respiratory function (cor pulmonale, emphysema, bronchial asthma, acute phase cerebrovascular disorder), cardiac disorder, renal disorder or organic disorder in the brain.
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 1/2 to 1 tablet (5 to 10 mg of the active ingredient) at a time, right before bedtime. For patients who newly start this medicine, treatment should be started at a dose of 1/2 tablet (5 mg) at a time. The dosage may be adjusted according to the age, symptoms or disease; however, the dose at a time should not exceed 1 tablet (10 mg). Strictly follow the instructions.
- Taking this medicine and having short sleeptime but need to be active after waking up, or need to wake up temporarily for work reasons, amnesia may occur. Do not take this medicine in these cases.
- If you miss a dose, take the missed dose if you can get sufficient sleep time until getting up the next morning. 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 change your prescribed dose on your own judgement or stop taking this medicine unless your doctor instructs you to do so because adverse reactions may occur.

Precautions while taking this medicine

- Symptoms of drug dependency such as desire to take a dose which is uncontrollable by yourself may occur if you continuously take this medicine, therefore you should avoid long-term use. If any of these symptoms occur, contact your doctor.
- The effect of this medicine may persist after the next morning and induce sleepiness as well as a decrease in attention, concentration and reflex movement, etc. Avoid operating dangerous machinery, such as driving a car.
- Alcohol intake before or after taking this medicine may enhance a decrease in mental function, perception or motor function. Refrain from alcohol drinking as far as possible.
- If you are breastfeeding, avoid breastfeeding while taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include lightheadedness, sleepiness, headache, feeling of residual sleepiness, dull headache, dizziness, anxiety, nightmare, hyperthymic, nausea, vomiting, loss of appetite, abdominal pain, palpitation, rash, itch, malaise, fatigue, feeling dull of lower limbs, double vision, thirst and discomfort. 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.

- inability to stop taking this medicine, anxiety/inability to sleep when reducing the dose or discontinuing this medicine [dependence, withdrawal symptom]
- hallucination, decreased consciousness, decreased judgement [psychiatric symptom, consciousness disturbance]
- inability to recall events that occurred before sleep or when the sleep was interrupted, semi-consciousness, suddenly get up and walk around unconsciously as if waking during sleep [transient anterograde amnesia, twilight state, parasomnia (sleepwalking symptoms, etc.)]
- breathing difficulty [respiratory depression]
- general malaise, loss of appetite, yellowing of the skin and the white of 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 reach of children. Store at room temperature (1 to 30 degrees Celsius), away from direct sunlight and moisture.
- Store split tablet pieces away from light.
- Discard the remainder. Do not store them. If you do not know how to discard, seek advice of your dispensing pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.