

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

Internal

Revised: 10/2022

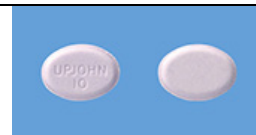
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

**Brand name:** Halcion Tablets 0.125mg

**Active ingredient:** Triazolam

**Dosage form:** pale purple tablet, major axis: 7.9 mm, minor axis: 5.7 mm, thickness: 2.2 mm

**Imprint or print on wrapping:** Halcion 0.125mg, ハルシオン 0.125mg, UPJOHN 10, トリアゾラム, 睡眠導入剤



**Effects of this medicine**

This medicine is a benzodiazepine sleep inducing drug that suppresses mechanism of emotion in the cerebral limbic system and the hypothalamus and mechanism of activation in the cerebral limbic system. It is usually used to treat insomnia and preanesthesia.

**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: acute angle-closure glaucoma, myasthenia gravis or decreased respiratory function caused by cor pulmonale/pulmonary emphysema/bronchial asthma or acute phase of cerebrovascular disorder, cardiac disorder, organic brain disorder, renal dysfunction or a history of it or liver disorder or a history of it.  
If you have presented with abnormal behavior as parasomnia (sleepwalking symptoms, etc.).  
If you are weakened.
- 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 treatment of insomnia: In general, for adults, take 2 tablets (0.25 mg of the active ingredient) at a time, immediately before bedtime. For patients with severe insomnia, the dosage may be increased up to 4 tablets (0.5 mg) at a time. It also may be adjusted according to the disease, age or symptoms. For elderly, the maximum single dose is 1 to 2 tablets (0.125 to 0.25 mg).  
For preanesthetic medication: In general, for adults, take 2 tablets (0.25 mg of the active ingredient) at a time, before bedtime on the evening before operation. The dosage may be increased up to 4 tablets (0.5 mg) at a time according to the disease, age or symptoms.  
In any case, strictly follow the instructions.
- If you have insomnia, do not take this medicine when you do not have enough time to sleep after taking it or you need to wake up temporarily for work reasons.
- If you miss a dose, you may take the missed dose when you have enough time until getting up in 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. Somnolence (falling asleep without stimulation), confusion (being distracted, answering incorrectly when asked, uncoordinated behavior), coordination disturbance (unable to move as intended, unable to do complex movements), slurred speech or coma (loss of consciousness, complete lack of response to stimulation) may occur as a result. As well, neuroleptic malignant syndrome (high fever, sweating, fuzzy head, trembling limbs, stiffness of the body, difficulty speaking, excess saliva, difficulty swallowing, quick pulse, increased respiration rate, increased blood pressure), respiratory depression (decreased respiration rate, shallow breathing), apnea, convulsive attack (muscle twitching in face and limbs, feeling confused transiently, decreased consciousness, muscle stiffness and trembling of limbs) may occur. If some symptoms occur concurrently while taking this medicine, discontinue the use of this medicine and get immediate medical attention. In some cases, administration of a large dose of this medicine or administration of this medicine with a large amount of alcohol may result in death.
- Do not stop taking this medicine unless your doctor instructs you to do so. Sudden dose reduction or discontinuation of this medicine may cause withdrawal symptoms, such as convulsive attack, delirium, tremor, insomnia, anxiety, hallucination and delusions.

**Precautions while taking this medicine**

- Symptoms such as sleepiness, dizziness, swaying feeling and loss of memory may occur.
- Continuous use of this medicine may cause symptoms of drug dependence, such as craving to take this medicine uncontrollably. You should avoid taking this medicine for a long period of time. If any of these symptoms occur, contact your doctor.
- Sleepiness and lacks of attention/concentration/reflex action ability may occur even after the following morning. Avoid driving a car or operating dangerous machinery.
- Avoid breastfeeding while taking this medicine.
- Drinking alcohol may intensify medicinal or medical effects. Avoid drinking during medication.
- Avoid taking grapefruit juice with this medicine, since it may intensify the therapeutic effects of this medicine.

#### **Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include sleepiness, light headedness, dull headache, headache, dizziness, incoordination, diarrhea 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.**

- (after medicine withdrawal) convulsive seizure, trembling limbs, anxiety [drug dependency, withdrawal symptom]
- stimulated excitement/confusion/aggression, hallucination/delusion, overexcited (emotionally hyper and loud) [mental symptoms]
- breathing becomes shallow and rapid, breathing difficulty, respiratory distress [respiratory depression]
- no memory during awakening at nighttime, semi-consciousness, behaving according to the content of dream and getting up to move [transient anterograde amnesia, twilight state, parasomnia (sleepwalking symptoms, etc.)]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [hepatitis, 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.
- Discard the remainder. Do not store them. If you do not know how to dispose of the unused medicines, seek advice of your 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.