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:ZOLPIDEM TARTRATE TABLETS 5mg「OHARA」

Active ingredient: Zolpidem tartrate

Dosage form:light orange tablet scored on the face, diameter: 6.6mm, thickness: 2.7mm

Imprint or print on wrapping:ゾルピデム酒石酸塩 5mg「オーハラ」, 5mg, 入眠剤, 就寝直前服用, Zolpidem Tartrate 5mg「OHARA」

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 for the treatment of insomnia (excluding insomnia resulting from 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 hepatic disorders, myasthenia gravis, acute angle closure glaucoma, experienced abnormal behavior during sleep when treated with this medicine in the past, decreased respiratory function due to cor pulmonale, pulmonary emphysema, bronchial asthma or acute phase cerebrovascular disorders, etc.
・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 to 2 tablets (5 to 10 mg of the active ingredient) at a time just before bedtime. For patients who newly start the medicine, treatment should be started at a dose of 1 tablet (5 mg) at a time. The dosage may be adjusted according to the patient's age, symptoms and disease; however, the dose at a time should not exceed 2 tablets (10 mg). Strictly follow the instructions.
・Since the medicine may cause amnesia, do not take it if you cannot take enough time to get started activities after getting up on the next morning or if you have to get up for temporarily work in the middle of the sleeping.
・If you have missed a dose, you may take the missed dose if you can get sufficient sleep time until getting up the next morning. DO NOT take double doses to make up for the missed dose.
・If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
・If you are taking the medicine continuously, do not change the dose or stop taking the medicine without the instructions of your doctor.

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.
・Alcohol intake just 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.
・The effect of the medicine may persist after the next morning and induce sleepiness as well as a decrease in attention, concentration, and reflex movement, etc. Do not drive a car, work at heights or operate dangerous machinery.
・If you are breastfeeding, avoid breastfeeding while taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, itch, light-headed feeling, sleepiness, headache, malaise, feeling of residual sleepiness and feeling queasy, etc. 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 the medicine, anxious feeling and inability to sleep when reducing the dose or discontinuing the medicine [dependency, withdrawal symptoms]
- ・delirium, hallucinations, depressed level of consciousness [psychiatric symptoms, disturbance of consciousness]
- ・inability to recall events that occurred before sleep or when the sleep was interrupted, dimmed consciousness, suddenly get up and walk around unconsciously as if waking during sleep [transient anterograde amnesia, twilight state, parasomnia (sleepwalking symptoms, etc.)]
- ・difficulty with breathing [respiratory depression]
- ・general malaise, loss of appetite, yellowing of the skin and the whites of the eye [hepatic function disorder, 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 at room temperature, away from light, heat and moisture.
- ・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.

SIE③