

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

Internal

Revised: 03/2017

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: RHYTHMY Tablets 1mg

Active ingredient: Rilmazafone hydrochloride hydrate

Dosage form: white tablet, diameter: 7.0 mm, thickness: 2.4 mm

Print on wrapping: (Face) リスミー 1mg, (Back) RHYTHMY 1mg リスミー 1mg 024 1



Effects of this medicine

This medicine is a benzodiazepine-type sleep inducer, and it acts on central nervous system and reduces neural activity in cerebral limbic system, thereby relieving anxiety and tension and inducing good sleep.

It is usually used for the treatment of insomnia, and for preanesthetic medication.

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, myasthenia gravis or decreased respiratory function caused by cor pulmonale, pulmonary emphysema, asthma, acute phase of cerebrovascular disorder, 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))
- Insomnia: In general, for adults, take 1 to 2 tablets (1 to 2 mg as the active ingredient) at a time, before bedtime.
- Preanesthetic medication: In general, for adults, take 2 tablets (2 mg as the active ingredient) at a time, before bedtime or operation.
In each case, the dosage may be adjusted according to your disease, age and symptoms. For the elderly, the maximum dose is 2 tablets (2 mg) at a time. Strictly follow the instructions.
- In case of using for insomnia, take this medicine just before bedtime. If there is a possibility you get out of bed temporarily after bedtime and do works, etc., do not take it.
- If you miss a dose, take one dose at the next time (before bedtime on the next day) in case of using for insomnia.
However, if you have more than 7 hours until scheduled wake-up time, you can take it as soon as you remember.
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. Sudden discontinuation of taking this medicine may cause adverse events.

Precautions while taking this medicine

- Since you may still have sleepiness on and after the next morning, or this medicine may cause decreased attention and concentration, avoid driving a car or operating dangerous machinery.
- Since drinking alcohol may enhance the effects or the adverse reactions of this medicine, avoid drinking alcohol.
- If you are breastfeeding, avoid breastfeeding while taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include drowsiness, feeling of continuous sleepiness, malaise, light-headed feeling and rash. 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.

- breathlessness, dizziness, faint or impaired consciousness [depressed respiration, carbon dioxide narcosis]
- (When stopping taking this medicine suddenly) feeling as if the thing which is not in fact were visible or audible, tremor (tremor in limbs), anxiety [dependence]
- disturbed consciousness, unable to have normal thoughts, disoriented [irritable excitation, confusion]
- no memory of events while arousal during sleep, twilight state [transient anterograde amnesia, twilight state]

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 the medicine out of the reach of infants and children. Store it at room temperature (1 to 30 degrees Celsius) away from direct sunlight and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.