

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

Internal

Revised: 02/2023

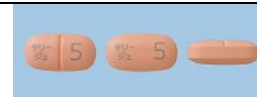
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic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

Brand name:TARLIGE TABLETS 5mg

Active ingredient:Mirogabalin besilate

Dosage form:reddish white tablet, major axis : 10.8 mm, minor axis : 5.7 mm, thickness : approx. 3.8 mm

Imprint or print on wrapping:タリージェ 5mg, Tarlige5mg, タリージェ 5



Effects of this medicine

This medicine inhibits calcium ions influx and suppresses release of neurotransmitters in the nervous system to reduce pain.

It is usually used to treat neuropathic pain.

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 renal dysfunction.
- 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, as an initial dose, take 1 tablet (5 mg of mirogabalin) at a time, twice a day. The dose will be increased by 1 tablet (5 mg) at a time and continue to take increased dose at intervals of one week or more, and eventually take 3 tablets (15 mg) at a time, twice a day. The dosage may be adjusted according to the age or symptoms in the 2 to 3 tablets (10 to 15 mg) range at a time, twice a day. Strictly follow the instructions.
- If you miss a dose, take the missed 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 dizziness, somnolence or loss of consciousness. Avoid operating dangerous machinery, such as driving a car. Especially for elderly patients, careful attention should be taken because there is a case resulted in falling and fracture due to these symptoms.
- This medicine may cause weight gain. If a sign of obesity appears, consult with your doctor or pharmacist.
- This medicine may cause blurred vision and double vision. If any of these symptoms are observed, consult with your doctor or pharmacist.
- Pay attention that alcohol may intensify medicinal or medical effects.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include somnolence, dizziness, edema and weight gain. 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.

- light headedness, state close to sleep with impaired consciousness, loss of consciousness [dizziness, somnolence, unconsciousness]
- general malaise, loss of appetite, nausea, vomiting, jaundice [liver dysfunction]

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 direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. If you do not know how to discard the remainder, ask your pharmacist or medical institution. Do not give the medicine to anyone else.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.