

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

Internal

Revised: 11/2020

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: Regnite Tablets 300mg

Active ingredient: Gabapentin enacarbil

Dosage form: white tablet, major axis: 15.1 mm, minor axis: 8.0 mm, thickness: 5.7 mm

Print on wrapping: (Face) 300mg, レグナイト, house-mark+731, 1日1回夕食後 house-mark, アステラス製薬, Regnite, レストレスレッグス症候群治療剤, (Back) nothing mentioned



Effects of this medicine

This medicine binds to the $\alpha_2\delta$ subunit of calcium channels, thereby suppresses transmission of abnormal sensations occurring in your legs, etc., while at rest, and improves symptoms of idiopathic restless legs syndrome. It is usually used for the treatment of moderate to severe idiopathic restless legs syndrome.

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 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, take 2 tablets (600 mg of the active ingredient) at a time, once a day, after supper. Strictly follow the instructions.
- This medicine is designed to release the active ingredient slowly. Follow instructions from your doctor or pharmacist when taking this medicine.
- Do not split, crush or grind the tablets. Take it without chewing.
- If you miss a dose, skip the missed dose for that day and follow your regular dosing schedule by taking the prescribed dose (after supper) from the following day. 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 weight gain. If signs of obesity occur, consult with your doctor or pharmacist.
- This medicine may cause sleepiness or decreased attentiveness/concentration/reflex motor capacity. Avoid driving a car or operating dangerous machinery.
- Foggy vision (blurred vision) or focus disorder (eyes have difficulty focusing) may occur after taking this medicine. If any symptoms occur, consult with your doctor or pharmacist.
- Avoid drinking alcohol with this medicine, since it affects the sustained release properties of this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include sleepiness and dizziness. 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.

- decreased urinary output, edema, general malaise [acute renal disorder]
- fever, loss of appetite, general malaise [oculomucocutaneous syndrome]
- rash, fever [drug-induced hypersensitivity syndrome]
- nausea/vomiting, general malaise, yellowing of the skin and the white of eyes [hepatitis, liver dysfunction, jaundice]
- muscle pain, weakness, reddish brown urine [rhabdomyolysis]

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 away from direct sunlight, heat and moisture.
- After opening the aluminum package, store the sheets containing this medicine in a dedicated storage bag.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.