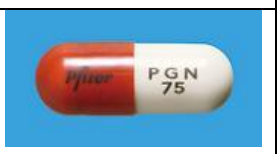
Drug Information Sheet("Kusuri-no-Shiori")

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:LYRICA Capsules 75mg

Active ingredient: Pregabalin
Dosage form:dark reddish-brown/white capsule, diameter: 5.3 mm, length: 14.3 mm
Imprint or print on wrapping:LYRICA 75mg, リリカ 75mg, VIATRIS, PGN 75, pfizer



Effects of this medicine

This medicine inhibits calcium influx and suppresses release of excitatory neurotransmitters such as glutamic acid in the central nervous system to tranquilize over-excited nerves and relieve pain.
It is usually used to treat neuropathic pain and pain associated with fibromyalgia.

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, congestive heart failure, a history of angioedema, tendency to drug dependence or its history or mental disorder.
・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))
・Neuropathic pain: In general, for adults, as an initial dose, take 75 mg of the active ingredient at a time, twice a day, and then the daily dosage may be gradually increased up to 300 mg in a week or more. The dosage may be adjusted according to the age or symptoms. However, the maximum daily dosage is 600 mg in two divided doses.
Pain associated with fibromyalgia: In general, for adults, as an initial dose, take 75 mg of the active ingredient at a time, twice a day. The daily dosage may be gradually increased up to 300 mg in a week or more and will be maintained at 300 to 450 mg. The dosage may be adjusted according to the age or symptoms. However, the maximum daily dosage is 450 mg in two divided doses.
This preparation contains 75 mg of the active ingredient in a capsule. In any case, 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 follow your regular dosing schedule. You should never take two doses at one time.
・If you accidentally take more than your prescribed dose, restlessness, agitation, falling asleep unless stimulated, confusional state, depression and convulsion may occur. If these symptoms appear at the same time, consult with your doctor immediately.
・Do not stop taking this medicine unless your doctor instructs you to do so. If you suddenly stop taking this medicine, insomnia, nausea, headache or diarrhea may occur.

Precautions while taking this medicine

・This medicine may cause dizziness, somnolence or loss of consciousness and there is a case resulted in car accident. Do not operate dangerous machinery such as driving a car while taking this medicine. Especially, if you are an elderly adult, pay close attention because there is a case resulted in falling and fracture due to these symptoms.
・This medicine may cause weight gain. Especially, if you increase dosage or take this medicine for a long period, weight gain may possibly occur. Weight check should be performed periodically, and consult with your doctor if you start to gain weight. You may be advised to improve content of meals and do exercises, etc.
・This medicine may cause reduced visual acuity, focus disorder, blurred vision or double vision. Consult with your doctor if any of them occurs.
・Pay attention that alcohol may intensify medicinal or medical effects.
・If you are breastfeeding, avoid breastfeeding while taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include dizziness, somnolence, 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.

・lightheadedness, state close to sleep with impaired consciousness, loss of consciousness [dizziness, somnolence, loss of consciousness]

・dyspnea, general edema, palpitation upon exertion [cardiac failure, pulmonary edema]
・muscle pain, lassitude, reddish brown urine [rhabdomyolysis]
・decreased urine output, edema of the limbs/face, malaise [renal failure]
・swelling of the face/tongue/lips/throat, hives, dyspnea [angioedema, shock, anaphylaxis]
・lassitude, malaise, cold sweat [hypoglycemia]
・dry cough, dyspnea, fever [interstitial pneumonia]
・high fever, bloodshot eyes, red rash [Stevens-Johnson syndrome, erythema multiforme]
・loss of appetite/nausea/vomiting, general malaise, jaundice, itch [fulminant hepatitis, 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 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.