Neurica

Pregabalin INN

Presentation

Neurica - 50 Capsule: Each capsule contains Pregabalin INN 50 mg.

Neurica - 75 Capsule: Each capsule contains Pregabalin INN 75 mg.

Description

Pregabalin is a structural derivative of the inhibitory neurotransmitter gamma-amino butyric acid (GABA). It does not bind directly to $GABA_A$, $GABA_B$ or benzodiazepine receptor. It is inactive at serotonin and dopamine receptors and does not inhibit dopamine, serotonin or nor-adrenaline reuptake. Pregabalin binds with high affinity to the alpha-2-delta site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system tissues. Oral bioavailability of Pregabalin is 90% that is independent of dose.

Indication

Neurica is indicated as adjunctive therapy for adult patients with partial onset of seizures and for the management of-

- Neuropathic pain associated with diabetic peripheral neuropathy
- Post-herpetic neuralgia
- Neuropathic pain associated with spinal cord injury
- Fibromyalgia

Dosage and Administration

Neuropathic pain associated with diabetic peripheral neuropathy: The maximum recommended dose of **Neurica** is 100 mg three times a day (300 mg/day) in patients with creatinine clearance of at least 60 ml/min. Dosing should begin at 50 mg three times a day (150 mg/day) and may be increased to 300 mg/day within 1 week based on efficacy and tolerability.

Post-herpetic neuralgia: The recommended dose of **Neurica** is 75 to 150 mg two times a day or 50 to 100 mg three times a day (150 to 300 mg/day) in patients with creatinine clearance of at least 60 ml/min. Dosing should begin at 75 mg two times a day or 50 mg three times a day (150 mg/day) and may be increased to 300 mg/day within 1 week based on efficacy and tolerability. Patients who do not experience sufficient pain relief following 2 to 4 weeks of treatment with 300 mg/day and who are able to tolerate **Neurica** may be treated with up to 300 mg two times a day or 200 mg three times a day (600 mg/day).

Adjunctive therapy for adult patients with partial onset seizures: **Neurica** at doses of 150 to 600 mg/day has been shown to be effective as adjunctive therapy in the treatment of partial onset seizures in adults. The total daily dose should be divided and given either two or three times daily. In general, it is recommended that patients should be started on a total daily dose not greater than 150 mg/day (75 mg two times a day or 50 mg three times a day). Based on individual patient response and tolerability, the dose may be increased to a maximum dose of 600 mg/day.

Management of fibromyalgia: The recommended dose of **Neurica** for fibromyalgia is 300 to 450 mg/day. Dosing should begin at 75 mg two times a day (150 mg/day) and may be increased to 150 mg two times a day (300 mg/day) within 1 week based on efficacy and tolerability. Patients who do not experience sufficient benefit with 300 mg/day may be further increased to 225 mg two times a day (450 mg/day).

Neuropathic pain associated with spinal cord injury: The recommended dose range is 150 to 600 mg/day. The recommended starting dose is 75 mg two times a day (150 mg/day). The dose may be increased to 150 mg two times a day (300 mg/day) within 1 week based on efficacy and tolerability. Patients who do not experience sufficient pain relief after treatment with 300 mg/day and who tolerate **Neurica** may be treated with up to 300 mg two times a day.

Patients with Renal Impairment

Since Pregabalin is eliminated primarily by renal excretion, so dosage adjustment is necessary in patients with reduced renal function.

Pregabalin Dosage Adjustment Based on Renal Function

Creatinine Clearance (ml/min)	Total Pregabalin Daily Dose (mg/day)*				Dose Regimen
≥60	150	300	450	600	BID or TID
30-60	75	150	225	300	BID or TID
15-30	25-50	75	100-150	150	QD or BID
< 15	25	25-50	50-75	75	QD

* Total daily dose (mg/day) should be divided as indicated by dose regimen to provide mg/dose.

Contraindication

Pregabalin is contraindicated in patients with known hypersensitivity to it or any of its components. Angioedema and hypersensitivity reactions may occure in patients receiving Pregabalin therapy.

Side Effect

The most common side effects include dizziness, somnolence, asthenia, confusion, peripheral edema, diplopia, blurred vision, abnormal thinking, nausea, tremor, vertigo, headache, dry mouth, weight gain.

Drug Interaction

Pregabalin may not be involved in significant pharmacokinetic drug interactions. Pregabalin does not show any pharmacokinetic interactions with antiepileptic drugs (Carbamazepine, Valproic acid, Gabapentine etc.) or any other drugs.

Precaution

Exercise caution when prescribing Pregabalin to patients who have had a previous episode of Angioedema. In addition, patients who are taking other drugs associated with Angioedema [e.g., angiotensin converting enzyme inhibitors (ACE-inhibitors)] may be at increased risk of developing angioedema.

Use in Pregnancy and Lactation

Pregnancy category C. So it should only be used if potential benefit justifies the potential risks to the fetus. ***Lactation:*** It is not known if Pregabalin is excreted in human milk but it is present in the milk of rats. So it should be used in nursing mother only if there is a clear benefit over the risk.

Overdose

There is no specific antidote for overdose with Pregabalin. Elimination of unabsorbed drug may be attempted by emesis or gastric lavage, observe usual precautions to maintain the airway.

Storage

Store in a cool & dry place, protect from light and moisture. Keep out of the reach of the children.

Commercial Pack

Neurica 50 Capsule: Each box contains 3 x 10 capsules in blister strips.

Neurica 75 Capsule: Each box contains 3 x 10 capsules in blister strips.

Manufactured by

GLOBE PHARMACEUTICALS LTD.

Bangladesh