Gabarol®

Pregabalin

Description

Gabarol® is the preparation of Pregabalin, which is an analogue of neurotransmitter gamma-amino-butyric acid (GABA). It does not bind directly to $GABA_A$ or $GABA_B$ or benzodiazepine receptors. It binds with high affinity to the $alpha_2$-delta site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system.

Indication and usage

Gabarol® is indicated for -

- Management of neuropathic pain associated with diabetic peripheral neuropathy
- Management of postherpetic neuralgia
- Adjunctive therapy for adult patients with partial seizures
- Management of fibromyalgia

Dose & administration

Adults over 18 years of age:

Gabarol® is given orally with or without food. Dosing amounts and frequency of dosing will be decided by the physician.

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

Postherpetic neuralgia: The recommended dose is 150 mg to 300 mg daily in 2-3 divided doses in patients with creatinine clearance of at least 60mL/min. Dosing should begin at 150 mg daily in 2-3 divided doses and may be increased to 300 mg/day within 1 week based on efficacy and tolerability.

Epilepsy: The initial dose is 150 mg daily in 2-3 divided doses as adjunctive therapy in the treatment of partial onset seizures in adults. In general, it is recommended that patients be started on a total daily dose not greater than 150 mg daily (75 mg two times a day, or 50 mg three times a day). Based on individual patient response and tolerability, the dosage may be increased to 300 mg daily in 2 divided doses after 1 week. The maximum dose of 600 mg daily given in 2 divided doses may be achieved after an additional week.

Fibromyalgia: The recommended dose is 300 to 450 mg daily. Dosing should being at 150 mg daily in two divided doses and may be increased to 300 mg daily in 2 divided doses within 1 week based on efficacy and tolerability. Patients who do not experience sufficient benefit with 300 mg daily may be further increased to 450 mg daily in 2 divided doses.

Children and adolescents (<18 years of age)

The safety and efficacy of Pregabalin has not been established in patients below the age of 18 years, with either epilepsy or neuropathic pain.

Use in elderly (Over 65 years of age)

Elderly patients may require a dose reduction of Pregabalin due to decreased renal function.

Patients with hepatic impairment

No dosage adjustment is required for patients with hepatic impairment.

Patients with renal impairment

Pregabalin is eliminated from the systemic circulation primarily by renal excretion as unchanged drug. As Pregabalin clearance is directly proportional to creatinine clearance dose reduction in patients with compromised renal function must be individualized according to creatinine clearance (CrCl), as indicated in below table:

Creatinine Clearance (ml/min)	**Starting dose (mg/day)**	**Maximum dose (mg/day)**	**Dosage regimen**
≥60	150	600	2-3 divided dose
≥30 - <60	75	300	2-3 divided dose
≥15 - <30	25 – 50	150	1-2 divided dose
< 15	25	75	Once daily
Supplementary dosage following haemodialysis (mg)			
	25	100	Single dose

Use in pregnancy and lactation

Pregnancy: Pregabalin is a pregnancy Category C drug. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: It is not know if Pregabalin is excreted in the breast milk of humans but because of the potential for tumorigenicity shown for Pregabalin in animal studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Precautions

Angioedema can occur, and may be associated with life-threatening respiratory compromise requiring emergency treatment. Pregabalin should be discontinued immediately in these cases. Hypersensitivity reactions (e.g. hives, dyspnea, and wheezing) can occur. Pregabalin should be discontinued immediately in these cases. Increased seizure frequency may occur in patients with seizure disorders if Pregabalin is rapidly discontinued. Withdraw Pregabalin gradually over a minimum of 1 week. Pregabalin may cause peripheral edema. Exercise caution when co-administering Pregabalin and Thiazolidinedione antidiabetic agents. Pregabalin may cause dizziness and somnolence and impair patients' ability to drive or operate machinery.

Side effects

Most common side effects are dizziness, somnolence, dry mouth, edema, blurred vision, weight gain and thinking abnormal (primarily difficulty with concentration/attention).

Drug interactions

There are no significant interactions between Pregabalin and other antiepileptic drugs like carbamazepine, valproic acid, lamotrigine, phenytoin, phenobarbital, and topiramate. Co administration of Pregabalin with the oral contraceptives like norethisterone and ethinyl oestradiol does not influence the steady state pharmacokinetics of either agent. Pregabalin may potentiate the effects of ethanol and lorazepam.

Contraindications

Pregabalin is contraindicated in patients with known hypersensitivity to Pregabalin or any of its other components.

Overdose

In overdose up to 15 mg, no unexpected adverse reactions were reported. The most common adverse events are affective disorder, somnolence, confusional state, depression, agitation and restlessness. Elimination of unabsorbed drug may be attempted by emesis or gastric lavage or hemodialysis if necessary.

Pharmaceutical precautions

Store in a cool and dry place. Protect from light.

Presentation

Gabarol® 25 mg capsule: Each capsule contains Pregabalin INN 25 mg.
Gabarol® 50 mg capsule: Each capsule contains Pregabalin INN 50 mg.
Gabarol® 75 mg capsule: Each capsule contains Pregabalin INN 75 mg.
Gabarol® 100 mg capsule: Each capsule contains Pregabalin INN 100 mg.
Gabarol® 150 mg capsule: Each capsule contains Pregabalin INN 150 mg.

Packaging quantities

Gabarol® 25 mg capsule: Carton of 30 capsules in blister pack.
Gabarol® 50 mg capsule: Carton of 30 capsules in blister pack.
Gabarol® 75 mg capsule: Carton of 30 capsules in blister pack.
Gabarol® 100 mg capsule: Carton of 20 capsules in blister pack.
Gabarol® 150 mg capsule: Carton of 20 capsules in blister pack.

® Registered Trade Mark

ACI Limited
Narayanganj, Bangladesh