GABA-P®

Pregabalin

Presentation

GABA-P® 50mg capsule: Each capsule caontains Pregabalin 50mg
GABA-P® 75mg capsule: Each capsule caontains Pregabalin 75mg

Indications & uses:

- Neuropathic pain associated with diabetic peripheral neuropathy
- Postherpetic neuralgia
- Adjunctive therapy for adult patients with partial onset seizures
- Fibromyalgia

DOSAGE AND ADMINISTRATION

GABA-P® is given orally with or without food.
When discontinuing GABA-P®, taper gradually over a minimum of 1 week.

Neuropathic pain associated with diabetic peripheral neuropathy

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. The maximum recommended dose of GABA-P® is 100 mg three times a day (300 mg/day) in patients with creatinine clearance of at least 60 mL/min. Because GABA-P® eliminated primarily by renal excretion, the dose should be adjusted for patients with reduced renal function.

Although GABA-P® was also studied at 600 mg/day, there is no evidence that this dose confers additional significant benefit and this dose was less well tolerated. In view of the dose-dependent adverse reactions, treatment with doses above 300 mg/day is not recommended .

Post herpetic neuralgia

The recommended dose of GABA-P® 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. Because GABA-P® is eliminated primarily by renal excretion, the dose should be adjusted for patients with reduced renal function .

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 GABA-P®, may be treated with up to 300 mg two times a day, or 200 mg three times a day (600 mg/day). In view of the dose-dependent adverse reactions and the higher rate of treatment discontinuation due to adverse reactions, dosing above 300 mg/day should be reserved only for those patients who have on-going pain and are tolerating 300 mg daily.

Adjunctive seizures therapy for adult patients with partial onset

GABA-P® 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 be started on a total daily dose no 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 GABA-P® 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). Although GABA-P® was also studied at 600 mg/day, there is no evidence that this dose confers additional benefit and this dose was less well tolerated. In view of the dose-dependent adverse reactions, treatment with doses above 450 mg/day is not recommended.

Patients with Renal Impairment

In view of dose-dependent adverse reactions and since GABA-P® is eliminated primarily by renal excretion, the dose should be adjusted in patients with reduced renal function. Dosage adjustment in patients with renal impairment should be based on creatinine clearance (CLcr). To use this dosing table, an estimate of the patient's CLcr in mL/min is needed. CLcr in mL/min may be estimated from serum creatinine (mg/dL) determination using the Cockcroft and Gault equation:

$$CLCr = \frac{140 - \text{age (years)} \times \text{weight (kg)}}{72 \times \text{serum creatinine (mg/dL)}} \times (0.85 \text{ for female patients})$$

For patients undergoing hemodialysis, GABA-P® daily dose should be adjusted based on renal function. In addition to the daily dose adjustment, a supplemental dose should be given immediately following every 4-hour hemodialysis treatment.

GABA-P® (Pregabalin) Dosage Adjustment Based on Renal Function

Creatinine Clearance (CL_{cr}) (mL/min)	Total Pregabalin Daily Dose*		Dose Regimen
	Starting dose (mg/day)	Maximum dose (mg/day)	
≥60	150	600	BID
30–60	75	300	QD or BID
15–30	25-50	150	QD or BID
< 15	25	75	QD
Supplementary dosage following hemodialysis (mg)			
	25	100	Single dose+

BID = Two divided doses
QD = Single daily dose
* Total dialy dose (mg/day) should be divided as indicated by dose regimen to provide mg/dose
+ Supplementary dose is a single additional dose

Precautions:

GABA-P® can cause drowsiness and dizziness. GABA-P® can cause vision problems, especially blurred vision or double vision.It can cause weight gain Studies suggest that GABA-P® increases the risk of fluid retention, especially in the arms, hands, legs, and feet. This can be a sign of congestive heart failure (especially if accompanied by difficulty breathing or chest pain). Fluid retention may also make congestive heart failure worse. GABA-P® can cause low platelets (a certain type of blood cells), which can increase your risk of bleeding. Studies suggest that GABA-P® can cause an irregular heart rhythm (arrhythmia).

Adverse reactions

Dizziness, drowsiness, visual disturbance (including blurred vision, diplopia), ataxia, dysarthria, tremor, lethargy, memory impairment, euphoria, constipation, dry mouth, peripheral edema, loss or decrease of libido, erectile dysfunction, weight gain , depression, confusion, agitation, hallucinations, myoclonus, hypoaesthesia, hyperaesthesia, tachycardia, excessive salivation, sweating, flushing, rash, muscle cramp, myalgia, arthralgia, urinary incontinence, dysuria, thrombocytopenia, kidney calculus , neutropenia, first degree heart block, hypotension, hypertension, pancreatitis, dysphagia, oliguria, rhabdomyolysis, suicidal thoughts or behavior.

Contraindications:

GABA-P® is contraindicated in patients with known hypersensitivity to preGABA-P or any of its other components.

Drug interactions:

Alcohol, benzodiazepines, and sleep medications are some of the drugs that can potentially interact with GABA-P®.

Use in Pregnancy & lactation:

Pregnancy category: C

Lactation: It is not known if GABA-P® is excreted in human milk; it is, however, present in the milk of rats. Because many drugs are excreted in human milk, and 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.

Storage condition:

Store in a cool & dry place,, protect from light and children.

How supplied:

GABA-P® 50mg capsule: Each box contains 3 blister strips of 10 capsules.
GABA-P® 75mg capsule: Each box contains 3 blister strips of 10 capsules.

® Trade Mark

Manufactured by :
RENATA LIMITED
Section VII, Milk Vita Road
Mirpur, Dhaka, Bangladesh