



Gabapen®

Gabapentin Tablet



Presentation

Gabapen® 100: Each film coated tablet contains Gabapentin USP 100 mg.
Gabapen® 300: Each film coated tablet contains Gabapentin USP 300 mg.

Description

Gabapentin is an anti-convulsant drug. It is a structural analog of gamma-amino-butyric-acid (GABA). All pharmacological actions following administration of gabapentin are due to the activity of parent compound. It increases brain GABA levels, binds to alpha-2-delta subunit of voltage-gated L-type Calcium channel, and inhibits branched chain amino acid transferase & probably inhibits neurotransmitter release of excitatory amino acids. Food has no effect on the rate and extent of absorption of gabapentin and it is not appreciably metabolized in human. Gabapentin is eliminated from the systemic circulation by renal excretion as unchanged drug. Elimination half-life is 5-7 hours and is unaltered by increased dose or following multiple dosing.



Indications and Uses

- **Neuralgia:** (a) pain from diabetic neuropathy, (b) post herpetic neuralgia
- **Partial seizures:** Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in patients over 3 years of age with epilepsy

Dosage and Administration

Neuropathic pain: 300 mg on day-1, then 300 mg twice on day-2, then 300 mg thrice on day-3, then increase the dose according to response in steps of 300 mg daily to maximum 1800 mg daily in three divided doses.

Partial seizure/epilepsy: 300 mg on day-1, then 300 mg twice on day-2, then 300 mg thrice on day-3, then increase the dose according to response in steps of 300 mg daily to maximum 2400 mg daily in three divided doses. *In case of children: For 3-12 years - 10 to 15 mg/kg, In case of titration 25-35 mg/kg daily in 3 divided doses. Maintenance dose is 900 mg daily (body weight 26-36 Kg) or 1.2 gm daily (body weight 37-50 Kg).*

In case of renal impaired patient Gabapentin doses must be reduced :

Renal clearance	Doses
>60	1200 mg/daily in 3 divided doses
30-60	600 mg/daily in 2 divided doses
15-30	300 mg/daily single dose
<15	150 mg/daily single dose or 300 mg/every alternate day
Heamodialysis	maximum 300 mg after each dialysis

Gabapentin can be taken orally with or without food.

Contraindications

Gabapentin is contraindicated in patients who have demonstrated hypersensitivity to the drug.

Precautions

Patients should be instructed to take Gabapentin only as prescribed.

While using Gabapentin patients should be instructed either not to drive a car or to operate other complex machinery until they have gained sufficient experiences about Gabapentin whether or not it affects their mental and/or motor performance adversely.

Side-effects

Generally Gabapentin is well tolerated but a few side effects like fatigue, dizziness, ataxia, weight gain, peripheral edema, dry mouth and somnolence, may occur. Rarely it may cause fulminate hepatic failure, or aplastic anemia.

Use in Pregnancy & Lactation

Pregnancy: Gabapentin 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: Gabapentin may be secreted through the breast milk like many other drugs, so it should be used in women who are nursing, only if the benefits clearly outweigh the risks.

Use in children

Safety and effectiveness of Gabapentin in the management of neuropathic pain in pediatric patients have not been established. Safety and effectiveness of Gabapentin in the management of seizures in pediatric patients below the age of 3 years have not been established.

Drug interactions

Antacids may reduce the bioavailability of Gabapentin by up to 20%. Cimetidine may alter its renal excretion. Gabapentin does not interact with other antiepileptic agent or with oral contraceptive preparation.

Overdosage

Overdosage of up to 30g has been reported. The symptoms consist of drowsiness, dizziness, slurred speech and mild diarrhea. Gabapentin can be removed by hemodialysis.

Storage

Do not store above 30° C. Keep away from light and out of the reach of children.

Commercial Pack

Gabapen® 100: Box containing 3 blister strips of 10 tablets.
Gabapen® 300: Box containing 3 blister strips of 10 tablets.

Manufactured by
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Savar, Dhaka, Bangladesh
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