

## Summary of prescribing information for GABAPIN tablets, capsules

**Active Ingredient:** each tablet of GABAPIN contains: gabapentin 100, 600, 800 mg. each capsule of GABAPIN contains: gabapentin 300, 400 mg. **Indication:** Epilepsy. **Dosage:** Patients 12 years of age and older: starting dose is 300 mg 3 times daily; may be titrated up to 600 mg 3 times daily. Patients 3 to 11 years of age: starting dose range is 10 to 15 mg/kg/day, given in 3 divided doses; recommended dose in patients 3 to 4 years of age is 40 mg/kg/day, given in three divided doses; the recommended dose in patients 5 to 11 years of age is 25 to 35 mg/kg/day, given in 3 divided doses. The recommended dose is reached by upward titration over a period of approximately 3 days. Dose should be adjusted in patients with reduced renal function. **Contraindications:** Known hypersensitivity to gabapentin or its ingredients. **Warning and precautions:** Drug Reaction with Eosinophilia and Systemic Symptoms (Multiorgan hypersensitivity): Discontinue if alternative etiology is not established. Anaphylaxis and Angioedema: Discontinue. Driving Impairment; Somnolence/Sedation and Dizziness: Warn patients not to drive until they have gained sufficient experience. Increased seizure frequency may occur in patients with seizure disorders if gabapentin is abruptly discontinued. Suicidal Behavior and Ideation: Monitor for suicidal thoughts/behaviour. Neuropsychiatric Adverse Reactions in Children 3 to 12 Years of Age: Monitor for events. **Pregnancy & Lactation:** Pregnancy: Based on animal data, may cause fetal harm. Lactation: Gabapentin is secreted in human milk following oral administration. The effects on the breastfed infant and on milk production are unknown. **Interaction:** Concentrations increased by morphine; may need dose adjustment. **Adverse reactions:** Most common Somnolence, dizziness, ataxia, fatigue, and nystagmus, viral infection, fever, nausea and/or vomiting, somnolence, and hostility. **Overdose:** symptoms double vision, slurred speech, drowsiness, lethargy, and diarrhea, coma. Management: general supportive care. Gabapentin can be removed by hemodialysis. Although hemodialysis may be indicated by the patient's clinical state or in patients with significant renal impairment.

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It is recommended to refer full prescribing information before prescription.

For further medical information, please write to: Intas Pharmaceuticals Ltd., Corporate House, Near Sola Bridge, SG highway, Thaltej, Ahmedabad-380054, Gujarat, India. [productqueries@intaspharma.com](mailto:productqueries@intaspharma.com)