

Summary of prescribing information for GABAPIN ME tablets

Active Ingredient: each film-coated tablet of GABAPIN ME contains: gabapentin + methylcobalamine (100mg + 500mcg; 300mg + 500 mcg). **Indication:** For the treatment of neuropathic pain in adults. **Dosage:** should be taken orally with or without food. The usual adult dose is 1 tablet 3 times a day. The optimum dose of gabapentin is 1800mg/day. The dosage should be adjusted according age, and severity of symptoms of the patient. **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. Methylcobalamin: Absorption of vitamin B₁₂ from the gastrointestinal tract may be reduced by neomycin, aminosalicylic acid, histamine H₂ receptor antagonists, omeprazole, and colchicine. Serum concentrations may be decreased by use of oral contraceptives. Many of these interactions are unlikely to be of clinical significance **Adverse reactions:** Most common Somnolence, dizziness, ataxia, fatigue, and nystagmus, viral infection, fever, nausea and/or vomiting, somnolence, and hostility. Methylcobalamin: occasionally cause anorexia, nausea, vomiting, and diarrhea. **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.

Prepared on 24th Feb 2020.

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