

Summary of prescribing information for GABAPIN PLUS tablets

Active Ingredient: each film-coated tablet of GABAPIN PLUS contains: gabapentin + Alpha-lipoic Acid + mecobalamin (100mg + 100mg + 500mcg; 300mg + 100mg + 500 mcg). **Indication:** treatment of pain associated with diabetic peripheral neuropathy in adults. **Dosage:** should be taken orally with or without food. Initiate with GABAPIN PLUS 300 tablets - 1 tablet taken once on day 1 (preferably in the evening), twice on day 2 (12 hours apart, BID), and thrice on day 3 (8 hours apart, TID). The dose can subsequently be titrated up as needed for pain relief to a daily dose of up to 6 tablets of GABAPIN PLUS 300 (in 3 divided doses) delivering 1800 mg gabapentin. If GABAPIN PLUS dose is reduced, discontinued or substituted with an alternative medication, this should be done gradually over a minimum of 1 week (a longer period may be needed at the discretion of the prescriber). **Contraindications:** Known hypersensitivity to gabapentin, alpha-lipoic acid, mecobalamin 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:** gabapentin: Concentrations increased by morphine; may need dose adjustment. Alpha-lipoic Acid: may lower blood glucose levels. Patients with diabetes on antidiabetic medication should have their blood glucose monitored and antidiabetic drug dose appropriately adjusted, if necessary, to avoid possible hypoglycemia. Mecobalamin: Absorption of vitamin B₁₂ from the gastrointestinal tract may be reduced by neomycin, aminosalicic 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:** gabapentin: Most common Somnolence, dizziness, ataxia, fatigue, and nystagmus, viral infection, fever, nausea and/or vomiting, somnolence, and hostility. Alpha-lipoic Acid: ALA is generally well tolerated. Most frequent, allergic reactions affecting the skin, including rashes, hives and itching, Gastrointestinal symptoms, including abdominal pain, nausea, vomiting and diarrhea, Malodorous urine (1200mg/day). Mecobalamin: 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.

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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