## GABAPENTIN IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

- Known sensitivity to Gabapentin or its ingredients

### WARNINGS AND PRECAUTIONS

- Drug Reaction with Eosinophilia and Systemic Symptoms (Multiorgan hypersensitivity): Discontinue if alternative etiology is not established
- Anaphylaxis and Angioedema: Discontinue and evaluate patient immediately
- Driving Impairment; Somnolence/Sedation and Dizziness: Warn patients not to drive until they have gained sufficient experience to assess whether their ability to drive or operate heavy machinery will be impaired
- Increased seizure frequency may occur in patients with seizure disorders if NEURONTIN is abruptly discontinued
- Suicidal Behavior and Ideation: Monitor for suicidal thoughts/behavior
- Neuropsychiatric Adverse Reactions in Children 3 to 12 Years of Age: Monitor for such events
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### ADVERSE REACTIONS

Most common adverse reactions (incidence ≥8% and at least twice that for placebo) were:

- Postherpetic neuralgia: Dizziness, somnolence, and peripheral edema
- Epilepsy in patients >12 years of age: Somnolence, dizziness, ataxia, fatigue, and nystagmus
- Epilepsy in patients 3 to 12 years of age: Viral infection, fever, nausea and/or vomiting, somnolence, and hostility

### DRUG INTERACTIONS

- Concentrations increased by morphine; may need dose adjustment

### Use in Specific Populations

- Pregnancy: Based on animal data, may cause fetal harm

**To report SUSPECTED ADVERSE REACTIONS, contact Acella Pharmaceuticals at 1-800-541-4802 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

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