Drug of the Month
Neurontin® Gabapentin
Treatment for postherpetic neuralgia and seizures

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use NEURONTIN safely and effectively. See full prescribing information for NEURONTIN. NEURONTIN® (gabapentin) capsules, for oral use NEURONTIN® (gabapentin) tablets, for oral use NEURONTIN® (gabapentin) oral solution Initial U.S. Approval: 1993

----------INDICATIONS AND USAGE----------

NEURONTIN is indicated for: • Postherpetic neuralgia in adults (1) • Adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy (1)

----------DOSAGE AND ADMINISTRATION----------

• Postherpetic Neuralgia (2.1) o Dose can be titrated up as needed to a dose of 1800 mg/day o Day 1: Single 300 mg dose o Day 2: 600 mg/day (i.e., 300 mg two times a day) o Day 3: 900 mg/day (i.e., 300 mg three times a day) • Epilepsy with Partial Onset Seizures (2.2) o Patients 12 years of age and older: starting dose is 300 mg three times daily; may be titrated up to 600 mg three times daily o Patients 3 to 11 years of age: starting dose range is 10 to 15 mg/kg/day, given in three 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 three 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 (2.3, 2.4)

----------DOSAGE FORMS AND STRENGTHS----------

• Capsules: 100 mg, 300 mg, and 400 mg (3) • Tablets: 600 mg, and 800 mg (3) • Oral Solution: 250 mg/5mL (3)

----------CONTRAINDICATIONS----------

Known hypersensitivity to gabapentin or its ingredients (4)

----------WARNINGS AND PRECAUTIONS----------

• Drug Reaction with Eosinophilia and Systemic Symptoms (Multiorgan hypersensitivity): Discontinue if alternative etiology is not established (5.1) • Anaphylaxis and Angioedema: Discontinue and evaluate patient immediately (5.2) • 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 (5.3, 5.4) • Increased seizure frequency may occur in patients with seizure disorders if NEURONTIN is abruptly discontinued (5.5) • Suicidal Behavior and Ideation: Monitor for suicidal thoughts/behavior (5.6) • Neuropsychiatric Adverse Reactions in Children 3 to 12 Years of Age: Monitor for such events (5.7)

----------ADVERSE REACTIONS----------

Most common adverse reactions (incidence ≥8% and at least twice that for placebo) were: • Postherpetic neuralgia: Dizziness, somnolence, and peripheral edema (6.1) • Epilepsy in patients >12 years of age: Somnolence, dizziness, ataxia, fatigue, and nystagmus (6.1) • Epilepsy in patients 3 to 12 years of age: Viral infection, fever, nausea and/or vomiting, somnolence, and hostility (6.1) To report SUSPECTED ADVERSE REACTIONS, contact Pfizer, Inc. at 1-800-438-1985 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

• Concentrations increased by morphine; may need dose adjustment (5.4, 7.2)

----------USE IN SPECIFIC POPULATIONS----------

• Pregnancy: Based on animal data, may cause fetal harm. (8.1)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide. Revised: 10/2017