

## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PREGABALIN CAPSULES safely and effectively. See full prescribing information for PREGABALIN CAPSULES. PREGABALIN capsules, for oral use CV

Initial U.S. Approval: 2004

### INDICATIONS AND USAGE

- Neuropathic pain associated with diabetic peripheral neuropathy (DPN) (1)
- Postherpetic neuralgia (PHN) (1)
- Adjunctive therapy for the treatment of partial-onset seizures in patients 17 years of age and older (1)
- Epilepsy (1)
- Neuropathic pain associated with spinal cord injury (1)

### DOSEAGE AND ADMINISTRATION

- For adult outpatients, begin dosing at 150 mg/day (2, 2, 3, 2, 3, 2, 3)
- Dosing recommendations:

INDICATION	Dosing regimen	Maximum Dose
DPN (par2)	3 divided doses per day	300 mg/day within 1 week
PHN (2,3)	2 or 3 divided doses per day	300 mg/day within 1 week Maximum dose of 600 mg/day
Adjunctive Therapy for Partial-Onset Seizures in Adult Patients 17 Years of Age and Older (2,4)	Maximum dose of 600 mg/day	
Fibromyalgia (2,5)	2 divided doses per day	300 mg/day within 1 week Maximum dose of 450 mg/day
Neuropathic Pain Associated with Spinal Cord Injury (2,6)	2 divided doses per day	300 mg/day within 1 week Maximum dose of 600 mg/day

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### INDICATIONS AND USAGE

- Management of neuropathic pain associated with diabetic peripheral neuropathy
- Management of postherpetic neuralgia
- Adjunctive therapy for the treatment of partial-onset seizures in patients 17 years of age and older
- Management of fibromyalgia
- Management of neuropathic pain associated with spinal cord injury

### DOSEAGE AND ADMINISTRATION

- Important Administration Instructions
- Neuropathic Pain Associated with Diabetic Peripheral Neuropathy in Adults
- Postherpetic Neuralgia in Adults
- Adjunctive Therapy for Partial-onset Seizures in Patients 17 Years of Age and Older
- Management of Fibromyalgia
- Management of Neuropathic Pain Associated with Spinal Cord Injury in Adults
- Dosing for Adult Patients with Renal Impairment

### CONTRAINDICATIONS

- Angiodema
- Hypersensitivity
- Increased Risk of Adverse Reactions with Abrupt or Rapid Discontinuation
- Subsidiary Behavior and Ideation
- Preexisting Disease
- Diagnosis and Surveillance
- Weight Gain
- Turquoise Pigment
- Ophthalmologic Effects
- Creatine Kinase Elevations
- PR Interval Prolongation

### ADVERSE REACTIONS

- Clinical Trial Experience
- Postmarketing Experience

### DRUG INTERACTIONS

### USE IN SPECIFIC POPULATIONS

- Pediatrics
- Geriatrics
- Renal Impairment
- Hepatic Impairment
- Pregnancy
- Lactation

### HOW SUPPLIED/STORAGE AND HANDLING

- How Supplied
- Storage and Handling

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## DOSEAGE FORMS AND STRENGTHS

- Capsules: 25mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg (1)

## CONTRAINDICATIONS

- Known hypersensitivity to pregabalin or any of its components (4)
- Angiodema (a swelling of the throat, head and neck) can occur, and may be associated with the following respiratory compromise requiring emergency treatment: Discontinue pregabalin immediately in Phase cases (5, 1)
- Hypersensitivity reactions (e.g., hives, dizziness, and wheezing) can occur. Discontinue pregabalin immediately in these patients (5, 2)
- Increased seizure frequency or other adverse reactions may occur if pregabalin is abruptly discontinued. Withdraw pregabalin gradually over a minimum of 1 week (5, 3)
- Opioid analgesics, including pregabalin, increase the risk of suicide thoughts or behaviors (5, 4)
- Pregabalin may cause peripheral edema. Exercise caution when co-administering pregabalin and vasoconstrictor antidiabetic agents (5, 5)
- Pregabalin may cause dizziness and somnolence and impair patient's ability to drive or operate machinery (5, 6)

## WARNINGS AND PRECAUTIONS

- Most common adverse reactions (greater than or equal to 5% and twice placebo) in adults are dizziness, somnolence, dry mouth, altered vision, blurred vision, weight gain and thinking abnormal (primarily during concentration) (8, 1)
- For report suspected adverse reactions, contact Novartis Pharmaceuticals LLC 1-800-688-2389 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

## USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause harm to fetus. Advise of potential risk to fetus (8, 1)
- Lactation: Breastfeeding is not recommended (8, 2)

## HOW TO OBTAIN ADDITIONAL INFORMATION

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## CLINICAL PHARMACOLOGY

- Mechanism of Action
- Pharmacokinetics
- Pharmacodynamics
- Renal Impairment
- Hepatic Impairment

## DRUG SAFETY AND EFFICACY

- Controlled Studies
- Observational Studies

## NONCLINICAL TOXICOLOGY

- Genotoxicity, Mutagenesis, Impairment of Fertility
- Animal Toxicology and/or Pharmacology

## CLINICAL STUDIES

- Neuropathic Pain Associated with Diabetic Peripheral Neuropathy
- Postherpetic Neuralgia
- Adjunctive Therapy for Partial-onset Seizures in Patients 17 Years of Age and Older
- Management of Fibromyalgia
- Management of Neuropathic Pain Associated with Spinal Cord Injury

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