

Lyrica (pregabalin) - Drug Summary

Parke-Davis Division of Pfizer Inc



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ADULT DOSAGE & INDICATIONS

Neuropathic Pain

Associated w/ Diabetic Peripheral Neuropathy:

Initial: 50mg tid (150mg/day)

Titrate: May increase to 300mg/day w/in 1 week prn

Max: 100mg tid (300mg/day)

Associated w/ Spinal Cord Injury:

Initial: 75mg bid

Titrate: May increase to 150mg bid (300mg/day) w/in 1 week prn

Max: 300mg bid (600mg/day) if no sufficient pain relief experienced following 2-3 weeks of treatment w/ 150mg

bid

Postherpetic Neuralgia

Initial: 75mg bid or 50mg tid (150mg/day)

Titrate: May increase to 300mg/day w/in 1 week prn

Max: 600mg/day divided bid or tid if no sufficient pain relief experienced following 2-4 weeks of treatment w/

300mg/day

Partial Onset Seizures

Adjunctive Therapy:

Initial: 150mg/day divided bid-tid

Titrate: May increase up to max dose of 600mg/day

Fibromyalgia

Initial: 75mg bid

Titrate: May increase to 150mg bid (300mg/day) w/in 1 week prn

Max: 225mg bid (450mg/day)

DOSING CONSIDERATIONS

Renal Impairment

Recommended Dose of 150mg/day BID or TID w/ Normal Renal Function:

CrCl 30-60mL/min: 75mg/day bid or tid CrCl 15-30mL/min: 25-50mg/day qd or bid

CrCl <15mL/min: 25mg/day qd

Recommended Dose of 300mg/day BID or TID w/ Normal Renal Function:

CrCl 30-60mL/min: 150mg/day bid or tid CrCl 15-30mL/min: 75mg/day qd or bid CrCl <15mL/min: 25-50mg/day qd

Recommended Dose of 450mg/day BID or TID w/ Normal Renal Function:

CrCl 30-60mL/min: 225mg/day bid or tid CrCl 15-30mL/min: 100-150mg/day qd or bid CrCl <15mL/min: 50-75mg/day qd

Recommended Dose of 600mg/day BID or TID w/ Normal Renal Function:

CrCl 30-60mL/min: 300mg/day bid or tid CrCl 15-30mL/min: 150mg/day qd or bid

CrCl <15mL/min: 75mg/day qd

Hemodialysis:

25mg qd Regimen: Take 1 supplemental dose of 25mg or 50mg 25-50mg qd Regimen: Take 1 supplemental dose of 50mg or 75mg 50-75mg qd Regimen: Take 1 supplemental dose of 75mg or 100mg 75mg qd Regimen: Take 1 supplemental dose of 100mg or 150mg

Discontinuation

Taper over minimum of 1 week

ADMINISTRATION

Oral route

HOW SUPPLIED

Cap: 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg; Sol: 20mg/mL [16 fl oz]

WARNINGS/PRECAUTIONS

Angioedema reported; d/c immediately if symptoms of angioedema with respiratory compromise occur. Caution in patients who had a previous episode of angioedema. Hypersensitivity reactions reported; d/c immediately if symptoms occur. Avoid abrupt withdrawal; gradually taper over a minimum of 1 week. Increased risk of suicidal thoughts/behavior; monitor for emergence or worsening of depression, suicidal thought/behavior, and/or unusual changes in mood/behavior. May cause weight gain and peripheral edema; caution with CHF. May cause dizziness and somnolence; may impair physical/mental abilities. New or worsening of preexisting tumors reported. Blurred vision, decreased visual acuity, visual field changes, and funduscopic changes reported. Creatine kinase (CK) elevations and rhabdomyolysis reported; d/c if myopathy is diagnosed or suspected or if markedly elevated CK levels occur. Associated with a decrease in platelet counts and PR interval prolongation. Caution in patients with renal impairment.

ADVERSE REACTIONS

Somnolence, dizziness, peripheral edema, ataxia, weight gain, dry mouth, fatigue, asthenia, blurred vision, diplopia, edema, nasopharyngitis, constipation, abnormal thinking, tremor.

DRUG INTERACTIONS

May increase risk of angioedema with other drugs associated with angioedema (eg, ACE inhibitors). Additive effects on cognitive and gross motor functioning with oxycodone, lorazepam, and ethanol. Caution with thiazolidinedione class of antidiabetic drugs; higher frequencies of weight gain and peripheral edema reported. Gabapentin reported to cause a small reduction in absorption rate. Reduced lower GI tract function (eg, intestinal obstruction, paralytic ileus, constipation) reported with medications that have the potential to produce constipation, such as opioid analgesics.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Gamma-aminobutyric acid derivative; not fully established; binds with high affinity to the α_2 -delta site (an auxiliary subunit of voltage-gated calcium channels) in CNS tissues.

PHARMACOKINETICS

Absorption: Well-absorbed; T_{max} =1.5 hrs (fasting), 3 hrs (fed). **Distribution:** V_d =0.5L/kg. **Metabolism:** Negligible metabolism. N-methylated derivative (major metabolite). **Elimination:** Urine (90% unchanged); $T_{d,p}$ =6.3 hrs

ASSESSMENT

Assess for hypersensitivity, renal impairment, preexisting tumors, history of drug abuse, history of depression, previous episode of angioedema, CHF, pregnancy/nursing status, and possible drug interactions. Obtain baseline weight.

MONITORING

Monitor for angioedema, hypersensitivity reactions, peripheral edema, weight gain, new tumors or worsening of preexisting tumors, ophthalmological effects, rhabdomyolysis, dizziness, somnolence, emergence or worsening of depression, suicidal thoughts or behavior, and/or changes in behavior. Monitor CK levels and platelet counts. Monitor ECG for PR interval prolongation.

PATIENT COUNSELING

Instruct to d/c therapy and seek medical attention if hypersensitivity reactions or symptoms of angioedema occur. Inform patients and caregivers to be alert for the emergence or worsening of depression, unusual changes in mood or behavior, or the emergence of suicidal thoughts or behavior; immediately report behaviors of concern to physician. Counsel that dizziness, somnolence, blurred vision, and other CNS signs and symptoms may occur; advise to use caution when operating machinery/driving. Inform that weight gain and edema may occur. Instruct not to abruptly/rapidly d/c therapy. Instruct to report unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever, to physician. Instruct not to consume alcohol while on therapy. Instruct to notify physician if pregnant, intending to become pregnant, breastfeeding or intending to breastfeed. Inform men on therapy who plan to father a child of the potential risk of male-mediated teratogenicity. Instruct diabetic patients to pay attention to skin integrity while on therapy.

STORAGE

 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

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