LYRICA®
PREGABALIN Ⓒ
capsules

Dosing Guide

LYRICA®


25 mg


50 mg


75 mg


100 mg


150 mg


200 mg


225 mg


300 mg

LYRICA® CR

(PREGABALIN EXTENDED RELEASE TABLETS)

82.5 mg

165 mg

330 mg

Capsules not actual size.

INDICATIONS

LYRICA is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy, management of postherpetic neuralgia, as adjunctive therapy for adult patients with partial onset seizures, management of fibromyalgia, and management of neuropathic pain associated with spinal cord injury.

LYRICA CR is indicated for the management of pain associated with diabetic peripheral neuropathy and management of postherpetic neuralgia. Efficacy of LYRICA CR has not been established for the management of fibromyalgia or as adjunctive therapy for adult patients with partial onset seizures.

IMPORTANT SAFETY INFORMATION

LYRICA and LYRICA CR are contraindicated in patients with known hypersensitivity to pregabalin or any of the components. Angioedema and hypersensitivity reactions have occurred in patients receiving pregabalin therapy.

There have been postmarketing reports of angioedema in patients during initial and chronic treatment with LYRICA. Specific symptoms included swelling of the face, mouth (tongue, lips, and gums), and neck (throat and larynx). There were reports of life-threatening angioedema with respiratory compromise requiring emergency treatment. Discontinue LYRICA or LYRICA CR immediately in patients with these symptoms. Patients who are taking other drugs associated with angioedema such as angiotensin-converting enzyme inhibitors (ACE inhibitors) may be at increased risk of developing angioedema. Exercise caution when using LYRICA or LYRICA CR in patients who have had a previous episode of angioedema.

Please see accompanying Full Prescribing Information, including Medication Guide, in pocket and additional Important Safety Information throughout.

Consider your next steps for **LYRICA** and **LYRICA CR** (pregabalin extended release tablets) **titration**, based on **efficacy** and **tolerability**

LYRICA

	DPN	FM	PHN	NeP SCI
STARTING DOSE (mg/day)	150* (50 mg TID)	150* (75 mg BID)	150* (Divided BID or TID)	150* (75 mg BID)
MINIMUM RECOMMENDED DOSE (mg/day)		300† (150 mg BID)	300‡ (Divided BID or TID)	300§ (150 mg BID)
MAXIMUM RECOMMENDED DOSE (mg/day)	300 (100 mg TID)	450 (225 BID)	600 (Divided BID or TID)	600 (300 mg BID)

*Dosage may be increased from 150 mg/day to 300 mg/day based on efficacy and tolerability within 1 week.

†For patients who do not experience sufficient benefit with 300 mg/day, the dosage may be increased to 450 mg/day.

‡Patients who do not experience sufficient benefit with 300 mg/day after 2 to 4 weeks of treatment and who are able to tolerate LYRICA may be titrated up to 600 mg/day.

§Patients who do not experience sufficient benefit with 300 mg/day after 2 to 3 weeks of treatment and who are able to tolerate LYRICA may be titrated up to 600 mg/day.

When discontinuing LYRICA, taper gradually over a minimum of 1 week

LYRICA CR

	DPN	PHN
STARTING DOSE (mg/day)	165‖ (Once daily)	165‖ (Once daily)
		330¶ (Once daily)
MAXIMUM RECOMMENDED DOSE (mg/day)	330 (Once daily)	660 (2x330 mg, once daily)

‖Dosage may be increased from 165 mg/day to 330 mg/day based on efficacy and tolerability within 1 week.

¶Patients who do not experience sufficient pain relief with 330 mg/day after 2 to 4 weeks of treatment and who are able to tolerate LYRICA CR may be titrated up to 660 mg/day.

When discontinuing LYRICA CR, taper gradually over a minimum of 1 week

LYRICA CR should be administered once daily after an evening meal. It should be swallowed whole and should not be split, crushed, or chewed.

Instruct patients that if they miss taking their dose of LYRICA CR after an evening meal, then they should take their usual dose of LYRICA CR prior to bedtime following a snack. If they miss taking the dose of LYRICA CR prior to bedtime, then they should take their usual dose of LYRICA CR following a morning meal. If they miss taking the dose of LYRICA CR following the morning meal, then they should take their usual dose of LYRICA CR at the usual time that evening following an evening meal.

Adjust the **LYRICA** and **LYRICA CR** daily dose based on **renal function**

LYRICA

CREATININE CLEARANCE (CLcr) (mL/min)	TOTAL LYRICA DAILY DOSE (mg/day)#				DOSE REGIMEN
≥60	150	300	450	600	BID or TID
30-60	75	150	225	300	BID or TID
15-30	25-50	75	100-150	150	QD or BID
<15	25	25-50	50-75	75	QD

#Total daily dose (mg/day) should be divided as indicated by dose regimen to provide mg/dose.

For patients undergoing hemodialysis, adjust the pregabalin daily dose based on renal function. In addition to the daily dose adjustment, administer a supplemental dose immediately following every 4-hour hemodialysis treatment.

Supplementary dosage following hemodialysis (mg)**

- Patients on the 25 mg QD regimen: take one supplemental dose of 25 mg or 50 mg
- Patients on the 25-50 mg QD regimen: take one supplemental dose of 50 mg or 75 mg
- Patients on the 50-75 mg QD regimen: take one supplemental dose of 75 mg or 100 mg
- Patients on the 75 mg QD regimen: take one supplemental dose of 100 mg or 150 mg

**Supplementary dose is a single additional dose.

LYRICA CR

CREATININE CLEARANCE (CLcr) (mL/min)	TOTAL LYRICA CR DAILY DOSE (mg/day)				DOSE REGIMEN
≥60	165	330	495††	660‡‡	Once daily
30-60	82.5	165	247.5§§	330	Once daily
<30/hemodialysis	Dose with LYRICA‖‖				

††495 mg = 3 × 165 mg tablets taken once daily.
‡‡660 mg = 2 × 330 mg tablets taken once daily.
§§247.5 mg = 3 × 82.5 mg tablets taken once daily.

‖‖LYRICA CR is not recommended for patients with CLcr less than 30 mL/min or who are undergoing hemodialysis. Please see LYRICA Capsules and Oral Solution USPI.

IMPORTANT SAFETY INFORMATION

There have been postmarketing reports of hypersensitivity reactions in patients shortly after initiation of treatment with LYRICA. Adverse reactions included skin redness, blisters, hives, rash, dyspnea, and wheezing. Discontinue LYRICA or LYRICA CR immediately in patients with these symptoms.

Antiepileptic drugs (AEDs) including pregabalin, the active ingredient in LYRICA and LYRICA CR, increase the risk of suicidal thoughts or behavior in patients taking AEDs for any indication. Monitor patients treated with any AED for any indication for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Pooled analyses showed clinical trial patients taking an AED had approximately twice the risk of suicidal thoughts or behavior than placebo-treated patients. The estimated incidence rate of suicidal thoughts or behavior among 27,863 AED-treated patients was 0.43%, compared to 0.24% among 16,029 placebo-treated patients, representing an increase of approximately 1 patient for every 530 patients treated with an AED.

Inform patients taking LYRICA or LYRICA CR that dizziness and somnolence may impair their ability to perform tasks such as driving or operating machinery. Concomitant use of LYRICA or LYRICA CR with other CNS depressants may exacerbate these effects.

In controlled studies, a higher proportion of patients treated with LYRICA reported blurred vision (7%) than did patients treated with placebo (2%), which resolved in a majority of cases with continued dosing. In controlled studies, 5% of patients treated with LYRICA CR reported blurred vision in the single-blind phase; less than 1% discontinued LYRICA CR treatment. Additionally, 1% of LYRICA CR-treated patients as compared to zero placebo-treated patients experienced

IMPORTANT SAFETY INFORMATION (cont'd)

blurred vision in the double-blind phase. Consider more frequent assessment for patients who are already routinely monitored for ocular conditions.

LYRICA and LYRICA CR may cause weight gain. LYRICA and LYRICA CR may cause peripheral edema in patients also taking thiazolidinedione antidiabetic drugs. Exercise caution when coadministering these drugs.

The most common adverse reactions across all LYRICA clinical trials are dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, constipation, euphoric mood, balance disorder, increased appetite, and thinking abnormal (primarily difficulty with concentration/attention).

The most common adverse reactions in LYRICA CR clinical trials were dizziness, somnolence, peripheral edema, fatigue, headache, nausea, blurred vision, weight gain, and dry mouth.

Advise nursing mothers that breastfeeding is not recommended during treatment with LYRICA or LYRICA CR.

LYRICA and LYRICA CR may exacerbate the effects of oxycodone, lorazepam, or ethanol on cognitive and gross motor functioning.

Carefully evaluate all patients treated with LYRICA or LYRICA CR for history of drug abuse and observe them for signs of LYRICA or LYRICA CR misuse or abuse (eg, development of tolerance, dose escalation, drug-seeking behavior).

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LYRICA® CR
PREGABALIN EXTENDED RELEASE TABLETS Ⓒ
once daily

Add 10% to your patient's **LYRICA** (pregabalin) dose when converting to **LYRICA CR** to achieve equivalent exposure

LYRICA Dosage (mg/day) (BID or TID)	LYRICA CR Dosage (mg/day) (QD)
150	165
300	330
600	660*†

*330 mg/day x 2.
†660 mg/day dosage strength is only prescribed for PHN patients.

When switching from **LYRICA** to **LYRICA CR**, on the day of the switch, the morning dose of **LYRICA** should be taken as prescribed, and **LYRICA CR** therapy should be initiated after an evening meal.

IMPORTANT SAFETY INFORMATION

Withdraw LYRICA or LYRICA CR gradually over a minimum of 1 week. Discontinue LYRICA or LYRICA CR immediately in patients with symptoms of hypersensitivity or angioedema.

LYRICA-treated patients with a creatinine clearance of 30 to 60 mL/min had a greater incidence of discontinuation due to adverse reactions than patients with normal creatinine clearance. Adjust the daily dose of LYRICA for patients with reduced renal function (creatinine clearance ≤60 mL/min) and in those undergoing hemodialysis. Administer a supplemental dose of LYRICA immediately following every 4-hour hemodialysis treatment.

LYRICA CR is not recommended for patients with creatinine clearance (CLcr) less than 30 mL/min or who are undergoing hemodialysis. Adjust the dose of LYRICA CR for patients with reduced renal function (CLcr ≤60 mL/min).

In standard, preclinical in vivo lifetime carcinogenicity studies of pregabalin, an unexpectedly high incidence of hemangiosarcoma was identified in 2 different strains of mice. The clinical significance of this finding is unknown. In clinical studies across various patient populations comprising 6396 patient-years of exposure in patients greater than 12 years of age, new or worsening preexisting tumors were reported in 57 patients.

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