Lyrinex CR

Pregabalin BP

COMPOSITION

Lyrinex CR 82.5 Tablet: Each film coated extended release tablet contains Pregabalin BP 82.5 mg.
Lyrinex CR 165 Tablet: Each film coated extended release tablet contains Pregabalin BP 165 mg.

PHARMACOLOGY

Pregabalin binds to the alpha-delta site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system. Although the mechanism of action of Pregabalin has not been fully elucidated, study results suggest that by binding to the alpha-delta subunit of the brain it gives anti-nociceptive and anti-seizure activities.

INDICATIONS

It is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN).

DOSAGE AND ADMINISTRATION

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

In case of Neuropathic Pain Associated with Diabetic Peripheral Neuropathy:

Starting dose is 165 mg once daily; may increase it to 330 mg once daily within 1 week based on individual patient response and tolerability. The maximum recommended dose of it is 330 mg once daily.

In case of Postherpetic Neuralgia:

Starting dose is 165 mg once daily; may increase it to 330 mg once daily within 1 week based on individual patient response and tolerability. Patients who do not experience sufficient pain relief following 2 to 4 weeks of treatment with 330 mg once daily and who are able to tolerate Pregabalin extended release tablet, may be treated with up to 660 mg once daily. The maximum recommended dose of it is 660 mg once daily.

Rules to take Pregabalin CR tablet instead of Pregabalin capsules:

Pregabalin Capsules (2 or 3 times daily)	Pregabalin CR Tablet (once a day)
75 mg/daily	1 tablet of 82.5 mg/day
150 mg/daily	1 tablet of 165 mg/day
225 mg/daily	3 tablet of 82.5 mg/day
300 mg/daily	2 tablet of 165 mg/day
450 mg/daily	3 tablet of 165 mg/day
600 mg/daily	4 tablet of 165 mg/day

Patients with Renal Impairment

Use of it is not recommended for patients with creatinine clearance (CLcr) less than 30 mL/min or who are undergoing hemodialysis. According to the creatinine clearance, dosage of Pregabalin CR tablet is as below:

Creatinine Clearance (CLcr)	Dosage & Administration
Greater than or equal to 60 mL/min	165 mg to 660 mg once daily
30-60 mL/min	82.5 mg to 330 mg once daily

When discontinuing it, taper gradually over a minimum of 1 week.

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

CONTRAINDICATIONS

It is contraindicated in patients who are hypersensitive to Pregabalin or any of its components.

WARNING & PRECAUTION

Angioedema: Angioedema [e.g., swelling of the face, mouth (tongue, lips, and gums) and neck (throat and larynx)] can occur. Discontinue it immediately in patients with these symptoms.

Hypersensitivity reactions: Hypersensitivity reactions (e.g., hives, dyspnea, and wheezing) can occur. Discontinue it immediately in these patients.

Suicidal behavior and ideation: Antiepileptic drug, Pregabalin increases the risk of suicidal thoughts or behavior.

Respiratory depression: May occur with it when used with concomitant CNS depressants or in the setting of underlying respiratory impairment. Monitor patients and adjust dosage.

Dizziness and somnolence: May cause dizziness and somnolence and impair patient's ability to drive or operate machinery.

Peripheral edema: May cause peripheral edema. Monitor patients for the development of edema when co-administering it and Thiazolidinedione antidiabetic agents.

Increased seizure frequency may occur in patients with seizure disorders if it is rapidly discontinued. So, withdraw it gradually over a minimum of 1 week.

SIDE EFFECTS

Most common side effects are dizziness, somnolence, headache, fatigue, peripheral edema, nausea, blurred vision, dry mouth and weight gain.

USE IN PREGNANCY & LACTATION

Pregnancy: There are no adequate and well-controlled studies with Pregabalin extended release tablets in pregnant women. In animal studies, it may cause fetal harm. Advise pregnant women of the potential risk to the fetus.
Lactation: During treatment breastfeeding is not recommended.

USE IN CHILDREN

The safety and effectiveness of it in paediatric patients have not been established.

DRUG INTERACTION

Pregabalin is predominantly excreted unchanged in the urine and does not bind to plasma proteins. So, its pharmacokinetics are unlikely to be affected by other agents. The interactions of it with other drugs have not been systematically evaluated.

OVERDOSAGE

In the post marketing report, the most commonly reported adverse events observed with Pregabalin when taken in overdose include reduced consciousness, depression/anxiety, confusional state and restlessness. Seizures and heart block have also been reported.
There is no specific antidote for overdose with Pregabalin. If indicated, elimination of unabsorbed drug may be attempted by emesis or gastric lavage; Pregabalin can be removed by hemodialysis.

STORAGE

Store below 30°C temperature in a dry place. Protect from light & moisture. Keep out of the reach of children.

02319/00

HOW SUPPLIED

Lyrinex CR 82.5 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.
Lyrinex CR 165 Tablet: Each box contains 24 tablets in Alu-Alu blister pack.

NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.