

Pergalin[®] (Capsules)



1350

Ref. No.:INS350/05.18

Pregabalin

Anti-epileptic

PERGALIN[®] 75MG CAPSULES

PRESENTATION:

Pergalin[®] 75 capsules : White crystalline powder filled in RED/WHITE colored hard gelatin capsule, plain on body and cap. Each capsule contains: Pregabalin 75 mg.

CLINICAL PHARMACOLOGY:

Pregabalin binds to an auxiliary subunit ($\alpha_2\text{-}\delta$ protein) of voltage-gated calcium channels in the central nervous system.

Pharmacokinetics:

Absorption

Pregabalin is rapidly absorbed when administered in the fasted state, with peak plasma concentrations occurring within 1 hour following both single and multiple dose administration. Pregabalin oral bioavailability is estimated to be $\geq 90\%$ and is independent of dose. Following repeated administration, steady state is achieved within 24 to 48 hours. The rate of Pregabalin absorption is decreased when given with food resulting in a decrease in C_{max} by approximately 25-30% and a delay in t_{max} to approximately 2.5 hours.

Distribution

In preclinical studies, Pregabalin has been shown to cross the blood brain barrier in mice, rats, and monkeys. Pregabalin has been shown to cross the placenta in rats and is present in the milk of lactating rats. Pregabalin is not bound to plasma proteins.

Biotransformation

Pregabalin undergoes negligible metabolism in humans. Following a dose of radiolabelled Pregabalin, approximately 98% of the radioactivity recovered in the urine was unchanged Pregabalin. The N-methylated derivative of Pregabalin, the major metabolite of Pregabalin found in urine, accounted for 0.9% of the dose.

Elimination

Pregabalin is eliminated from the systemic circulation primarily by renal excretion as unchanged drug. Pregabalin mean elimination half-life is 6.3 hours. Pregabalin plasma clearance and renal clearance are directly proportional to creatinine clearance.

USES:

Neuropathic pain

Pergalin[®] is indicated for the treatment of peripheral and central neuropathic pain in adults.

Epilepsy

Pergalin[®] is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation.

Generalised anxiety disorder

Pergalin[®] is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.

DOSAGE AND ADMINISTRATION:

The dose range is 150 to 600 mg per day given in either two or three divided doses.

Neuropathic pain

Pregabalin treatment can be started at a dose of 150 mg per day given as two or three divided doses.

Epilepsy

Pregabalin treatment can be started with a dose of 150 mg per day given as two or three divided doses. Based on individual patient response and tolerability, the dose may be increased to 300 mg per day after 1 week. The maximum dose of 600 mg per day may be achieved after an additional week.

Generalised anxiety disorder

The dose range is 150 to 600 mg per day given as two or three divided doses.

Pergalin®

CONTRA-INDICATIONS AND WARNINGS:

Hypersensitivity to the active substance or to any of the excipients.

SPECIAL WARNING AND PRECAUTIONS

Diabetic patients

In accordance with current clinical practice, some diabetic patients who gain weight on Pregabalin treatment may need to adjust hypoglycaemic medicinal products.

Dizziness, somnolence, loss of consciousness, confusion and mental impairment

Pregabalin treatment has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in the elderly population. There have also been post marketing reports of loss of consciousness, confusion and mental impairment. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medicinal product.

Vision-related effects

In controlled trials, a higher proportion of patients treated with Pregabalin reported blurred vision than did patients treated with placebo which resolved in a majority of cases with continued dosing. In the clinical studies where ophthalmologic testing was conducted, the incidence of visual acuity reduction and visual field changes was greater in Pregabalin-treated patients than in placebo-treated patients; the incidence of fundoscopic changes was greater in placebo-treated patients. In the post marketing experience, visual adverse reactions have also been reported, including loss of vision, visual blurring or other changes of visual acuity, many of which were transient.

Renal failure

Cases of renal failure have been reported and in some cases discontinuation of Pregabalin did show reversibility of this adverse reaction. Doses should be reduced in renal impairment.

Adverse Effects:

Common or very common: Appetite changes, blurred vision, confusion, constipation, diplopia, disturbances in muscle control and movement dizziness, drowsiness.

Uncommon: Abdominal distension, abnormal dreams, agitation, arthralgia, chills, cognitive impairment, depersonalisation, depression, dry eye, dyspnoea.

Rare: Arrhythmia, ascites, bradycardia, breast discharge, breast hypertrophy, breast pain, cold extremities.

Overdosage:

In the post marketing experience, the most commonly reported adverse reactions observed when Pregabalin was taken in overdose included somnolence, confusional state, agitation, and restlessness. Seizures were also reported. In rare occasions; cases of coma have been reported. Treatment of Pregabalin overdose should include general supportive measures and may include haemodialysis.

PHARMACEUTICAL PRECAUTIONS:

Store in a dry place below 30°C. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:

Prescription Only Medicine (POM)

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