PRENEU Capsules

(Pregabalin Capsules BP)

پرینئو کیپسولز

(پریگابالن کیپسولز بی پی)

COMPOSITION:
Preneu 50mg: Each capsule contains: Pregabalin BP …..... 50mg
Preneu 75mg: Each capsule contains: Pregabalin BP …..... 75mg
Preneu 100mg: Each capsule contains: Pregabalin BP … 100mg
Preneu 150mg: Each capsule contains: Pregabalin BP … 150mg
[BP Specs.]

DESCRIPTION: Preneu (Pregabalin) is an analogue of the neurotransmitter gamma-aminobutyric acid (GABA). It has analgesic and anti-convulsant activity. **Preneu** (Pregabalin) is described chemically as (S)-3-(aminomethyl)-5-methylhexanoic acid.

CLINICAL PHARMACOLOGY:
Mode of Action: Pregabalin reduces neuronal calcium current by binding to the α_2-δ subunit of voltage gated calcium channels in CNS tissues and this particular mechanism may be responsible for effects in neuropathic pain, anxiety and other pain syndromes. Pregabalin does not block sodium channels, is not active at opiate receptors, and does not alter cyclooxygenase enzyme activity. It is inactive at serotonin and dopamine receptors and does not inhibit dopamine, serotonin or noradrenaline reuptake.

Pharmacokinetics:
Absorption: Following oral administration of Pregabalin under fasting conditions, peak plasma concentrations occur within 1.5 hours. Pregabalin oral bioavailability is >90% and is independent of dose. Following single (25 to 300mg) and multiple dose (75 to 900mg/day) administration, maximum plasma concentrations (C_{max}) and area under the plasma concentration-time curve (AUC) values increase linearly. Following repeated administration, steady state is achieved within 24 to 48 hours.
Distribution: Pregabalin does not bind to plasma proteins. The apparent volume of distribution of Pregabalin following oral administration is approximately 0.5L/Kg.
Metabolism: Pregabalin undergoes negligible metabolism in humans.
Elimination: About 98% of the dose is excreted in the urine as unchanged drug. The N-methylated derivative of Pregabalin, found in urine, accounted for 0.9% of the dose. Pregabalin mean elimination half-life is 6.3 hours and is eliminated from the systemic circulation primarily by renal excretion as unchanged drug. Pregabalin is removed by haemodialysis.
Special Populations: Renal Impairment: Pregabalin plasma clearance and renal clearance are directly proportional to creatinine clearance. Pregabalin clearance is reduced in patients with impaired renal function. Dose adjustments are required in patients with renal impairment (CLcr < 60L/min). Pregabalin is effectively removed by haemodialysis (following 4 hour haemodialysis treatment plasma Pregabalin concentrations are reduced by approximately 50%). Dose adjustments are required for patients on haemodialysis.
Elderly (Over 65 years of age): Pregabalin clearance tends to decrease with increasing age. This decrease in Pregabalin oral clearance is consistent with decrease in creatinine clearance associated with increasing age. Reduction of Pregabalin dose may be required in patients who have age related compromised renal function.

INDICATIONS: Preneu (Pregabalin) Capsule is indicated for: For the management of neuropathic pain associated with diabetic peripheral neuropathy. For the management of postherpetic neuralgia. For the treatment of pain associated with spinal cord injury. As adjunctive therapy for adult patients with partial onset seizures with or without secondary generalization. For the treatment of Generalized Anxiety Disorder (GAD) in adults & for the treatment Fibromyalgia Syndrome (FMS).

CONTRA-INDICATIONS: Pregabalin is contra-indicated in patients with known hypersensitivity to Pregabalin or any of the components of the product. Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.

DOSAGE AND ADMINISTRATION:
Neuropathic Pain Associated with Diabetic Peripheral Neuropathy: The maximum recommended dose of **Preneu** (Pregabalin) Capsule is 100mg three times a day (300mg/day) in patients with creatinine clearance of at least 60mL/min. Dosing should start at 50mg 3 times a day (150mg/day) and may be gradually increased to 300mg/day within 1 week based on efficacy and tolerability. Since **Preneu** (Pregabalin) Capsule is eliminated primarily by renal excretion, the dose should be adjusted for patients with reduced renal function.
Postherpetic Neuralgia: Dose of **Preneu** (Pregabalin) Capsule is 75 to 150mg two times a day or 50 to 100mg 3 times a day (150 to 300mg/day) in patients with creatinine clearance of at least 60mL/min. Dose should be started at 75mg 2 times a day or 50mg 3 times a day (150mg/day) and may be increased to 300mg/day within 1 week based on efficacy and tolerability. Patients who does not have sufficient pain relief following 2 to 4 weeks of treatment with 300mg/day, and who are able to tolerate **Preneu** (Pregabalin) Capsule, may be treated with up to 300mg two times a day, or 200mg three times a day (600mg/day).
Neuropathic Pain Associated with Spinal Cord Injury: The recommended daily dose is 75mg two times a day (150mg/day). The dose may be increased to 150mg two times a day (300mg/day) within 1 week based on efficacy and tolerability. Patients who do not experience sufficient pain relief following 2 to 4 weeks of treatment with 300mg/day and who are able to tolerate **Preneu** (Pregabalin) Capsule, may be treated with up to 300mg two times a day (600mg/day).
Adjunctive Therapy for Adult Patients with Partial Onset Seizures: Dose of **Preneu** (Pregabalin) Capsule 150 to 600mg/day has been shown to be effective as adjunctive

Rev: 04-22/3/NQ

therapy in the treatment of partial onset seizures in adults. The total daily dose should be divided into two or three times daily. Since **Preneu** (Pregabalin) Capsule is eliminated primarily by renal system, the dose should be adjusted for patients with reduced renal function.
General Anxiety Disorder: The dose range is 150 to 600mg/day given as two or three divided doses. The need for treatment should be reassessed regularly. **Preneu** (Pregabalin) Capsule treatment can be started with a dose of 150mg/day given as 2-3 divided doses. Based on individual patient response and tolerability, the dose may be increased to 300mg/day after 1 week. Following an additional week, the dose may be increased to 450mg/day. The maximum dosage of 600mg/day may be achieved after an additional week.
Management of Fibromyalgia Syndrome (FMS): Recommended dose of **Preneu** (Pregabalin) Capsule for the treatment of Fibromyalgia Syndrome (FMS) is 300 to 450mg/day. Dosing should start at 75mg two times a day (150mg/day) and may be increased to 150mg two times a day (300mg/day) within 1 week based on efficacy and tolerability. Patients who do not experience sufficient benefit with 300mg/day may be further increased to 225mg two times a day (450mg/day).
Patients with Renal Impairment: With reference to dose-dependent adverse reactions and as **Preneu** (Pregabalin) Capsule is eliminated primarily by renal excretion, the dose should be adjusted in patients with reduced renal function. Dosage adjustment in patients with renal impairment should be based on creatinine clearance (CLcr).

OVERDOSAGE: There is no specific treatment or antidote for overdose with Pregabalin. If indicated, elimination of unabsorbed drug may be attempted by emesis or gastric lavage, usual precautions should be observed to maintain the airway. General supportive care of the patient is indicated including monitoring of vital signs and observation of the clinical status of the patient and may include haemodialysis.

PRECAUTIONS: Withdrawal of Antiepileptic Drugs (AEDs): As with all AEDs, Pregabalin should be withdrawn gradually to minimize the potential of increased seizure frequency in patients with seizure disorders. If Pregabalin is discontinued this should be done gradually over a minimum of 1 week.
Angioedema: Pregabalin should be discontinued immediately if symptoms of angioedema, such as facial, perioral or upper airway swelling occur.
Weight Gain: Pregabalin associated weight gain is related to dose and duration of exposure. Some diabetic patients who gain weight on Pregabalin treatment may need to adjust hypoglycaemic medications.
Discontinuation: After discontinuation of short-term and long-term treatment with Pregabalin withdrawal symptoms have been observed in some patients.
The following events have been mentioned: Insomania, headache, nausea, diarrhoea, flu syndrome, nervousness, depression, pain, sweating and dizziness.
Creatinine Kinase Elevation: Pregabalin should be discontinued if myopathy is diagnosed or suspected or if markedly elevated creatinine kinase levels occur.
Congestive Heart Failure (CHF): There have been reports of congestive heart failure in some patients receiving Pregabalin. These reactions are mostly seen in elderly cardiovascular compromised patients during Pregabalin treatment for a neuropathic indication. Pregabalin should be used with caution in these patients. Discontinuation of Pregabalin may resolve the reaction.
Alcohol: Patients should be told to avoid consuming alcohol while on Pregabalin, as it may potentiate the impairment of motor skills and sedation of alcohol.
Effects on Ability to Drive and Use Machines and Injuries: Pregabalin may cause dizziness and somnolence and therefore may have an influence on the ability to drive or use machines or may increase the occurrence of accidental injuries especially in the elderly population.
Paediatric Use: The safety and efficacy of Pregabalin in paediatric patients have not been established.
Pregnancy: There are no adequate and well-controlled studies in pregnant women. Pregabalin should be used during pregnancy only if the potential benefit justifies the potential risk to fetus.
Lactation: It is not known whether Pregabalin is excreted into human milk. Because many drugs are excreted in human milk, caution should be exercised when Pregabalin is administered to a nursing mother.

SIDE EFFECTS: Most common: Dizziness, drowsiness and somnolence.
Common: Increased appetite, euphoric mood, confusion, irritability, decrease in libido, disorientation, insomnia, ataxia, abnormal coordination, tremor, dysarthria, memory impairment, disturbance in attention, paraesthesia, sedation, balance disorder, lethargy, headache, blurred vision, diplopia, vertigo, vomiting, dry mouth, constipation, flatulence, erectile dysfunction, gait abnormal, feeling drunk, fatigue, peripheral oedema, oedema and weight gain.

DRUG INTERACTIONS: Patients who require concomitant treatment with CNS depressants such as opiates or benzodiazepines should be informed that they may experience additive CNS side effects such as somnolence. Pregabalin may potentiate the effects of ethanol and lorazepam. There are also some reports of respiratory failure and coma in patients taking Pregabalin and CNS depressant medications. Pregabalin appears to be additive in the impairment of cognitive and gross motor function caused by oxycodone.

INSTRUCTIONS: Store below 30°C. Protect from heat, light and moisture. Keep out of the reach of the children.

PRESENTATION: Preneu (Pregabalin) Capsule 50mg, 75mg, 100mg and 150mg is available in pack of 14's.

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
NABIQASIM INDUSTRIES (PVT.) LTD.
17/24, Korangi Industrial Area, Karachi-Pakistan.
PHARMA
Rev: 04-22/3/NQ