PG®

Pregabalin INN Capsule

DESCRIPTION

PG® is the preparation of Pregabalin, used for the treatment of neuropathic pain and as an adjunctive therapy for partial seizures epilepsy. The active substance, Pregabalin, is a gamma-aminobutyric acid analogue (S)-3-(aminomethyl)-5-methylhexanoic acid. Pregabalin binds to an auxiliary subunit (α_2-δ protein) of voltage-gated calcium channels in the central nervous system, potently displacing [H] - gabapentin.

INDICATIONS

- Neuropathic pain: **PG®** is indicated for the treatment of peripheral neuropathic pain including diabetic peripheral neuropathy in adults
- **Epilepsy: PG®** is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalization
- Fibromyalgia
- Post Herpetic Neuralgia
- Generalized Anxiety Disorder

DOSAGE AND ADMINISTRATION

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

PG® may be taken with or without food.

Neuropathic pain:

- Administer in 3 divided doses per day
- Begin dosing at 150 mg per day
- May be increased to a maximum of 300 mg per day within 1 week

Epilepsy:

- Administer in 2 or 3 divided doses per day
- Begin dosing at 150 mg per day
- Maximum dose of 600 mg per day

Fibromyalgia :

- Administer in 2 divided doses per day
- Begin dosing at 150 mg per day
- May be increased to 300 mg per day within 1 week
- Maximum dose of 450 mg per day

Post Herpetic Neuralgia :

- Administer in 2 or 3 divided doses per day
- Begin dosing at 150 mg per day
- May be increased to 300 mg per day within 1 week
- Maximum dose of 600 mg per day

Generalized Anxiety Disorder :

- Administer in 2 or 3 divided doses per day
- Begin dosing at 150 mg per day
- Maximum dose of 600 mg per day

Dose should be adjusted in patients with reduced renal function.

Administration in Renal Impairment:

Pregabalin clearance is directly proportional to creatinine clearance, so dosage reduction in patient with compromised renal function must be adjusted according to creatinine clearance (Clcr).

$$\text{CLCr} = \frac{[140\text{-age (years)}] \times \text{weight (kg)}}{72 \times \text{serum creatinine (mg/dL)}} \quad (\times 0.85 \text{ for female patients})$$

Discontinuation of Pregabalin:

In accordance with current clinical practice, if Pregabalin has to be discontinued, it is recommended to withdraw gradually over a minimum of 1 week.

CONTRAINDICATIONS

Pregabalin is contraindicated in patients with known hypersensitivity to Pregabalin or any of its components.

USE IN PREGNANCY AND LACTATION

Pregnancy category C. Breast-feeding is not recommended during treatment with Pregabalin.

SIDE EFFECTS

Dizziness, somnolence, vision blurred, fatigue, weight increased, dry mouth, ataxia, peripheral edema, diplopia, tremor, constipation, confusion, lethargy, memory impairment, appetite increased & oedema etc.

PRECAUTIONS

It is advised not to drive a car or operating dangerous machineries. While taking Pregabalin, some patients with diabetes who gain weight may need to alter their diabetic medications. Alcohol should be avoided while taking this medicine. Patients with renal insufficiency should take Pregabalin with proper caution & dose adjustment should be done according to creatinine clearance.

PHARMACEUTICAL PRECAUTION

Store in a dry place & away from light. Keep out of reach of children.

PACKAGING

PG® 25 Capsule : Box containing 4 strips of 6 capsule each. Each capsule contains Pregabalin INN 25 mg.

PG® 50 Capsule : Box containing 5 strips of 6 capsule each. Each capsule contains Pregabalin INN 50 mg.

PG® 75 Capsule : Box containing 5 strips of 6 capsule each. Each capsule contains Pregabalin INN 75 mg.

SK+F

Manufactured by:
ESKAYEF PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH
® REGD.TRADEMARK

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