



Venpa®

Pregabalin USP

Presentation

Venpa® 25 mg capsule:

Each capsule contains Pregabalin USP 25 mg.

Venpa® 50 mg capsule:

Each capsule contains Pregabalin USP 50 mg.

Venpa® 75 mg capsule:

Each capsule contains Pregabalin USP 75 mg.

Description

Pregabalin is a structural derivative of gamma-amino-butyric acid (GABA). It does not bind directly to GABA_A, GABA_B & benzodiazepine receptors. It binds with high affinity to the alpha-2-delta site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system tissues. Oral bioavailability of Pregabalin is 90%. Pregabalin is eliminated largely by renal excretion and has an elimination half-life of about 6 hours. Pregabalin can be taken with or without food.

Indications

1. Neuralgia:

- Pain from diabetic neuropathy
- Postherpetic neuralgia

2. Partial seizure/epilepsy:

- Pregabalin is also indicated as adjunctive therapy for adult patients with partial-onset seizures

3. Can be used for the management of Fibromyalgia & Neuropathic pain associated with spinal cord injury.

Dosage and administration

Diabetic neuropathic pain:

The maximum recommended dose of Pregabalin is 100 mg three times a day in patients with creatinine clearance of at least 60 mL/min. Dosing should begin at 50 mg three times a day and may be increased to 300 mg/day within 1 week based on efficacy and tolerability.

Postherpetic neuralgia:

The recommended dose of Pregabalin is 75 to 150 mg two times a day or 50 to 100 mg three times a day in patients with creatinine clearance of at least 60 mL/min. Dosing should begin at 75 mg two times a day or 50 mg three times a day and may be increased to 300 mg/day within 1 week based on efficacy and tolerability.

Epilepsy:

The recommended dose of Pregabalin is 150 to 600 mg/day as adjunctive therapy in the treatment of partial onset seizures in adults.

Management of Fibromyalgia:

The recommended dose of Pregabalin for Fibromyalgia is 300 to 450 mg/day. Dosing should begin at 75 mg two times a day (150 mg/day) and may be increased to 150 mg two times a day (300 mg/day) within 1 week based on efficacy and tolerability. Patients who do not experience sufficient benefit with 300 mg/day may be further increased to 225 mg two times a day (450 mg/day).

Neuropathic pain associated with spinal cord injury:

The recommended dose range is 150 to 600 mg/day. The recommended starting dose is 75 mg two times a day (150 mg/day). The dose may be increased to 150 mg two times a day (300 mg/day) within 1 week based on efficacy and tolerability. Patients who do not experience sufficient pain relief after treatment

Insert for prescribing information

with 300 mg/day and who tolerate Pregabalin may be treated with up to 300 mg two times a day. Venpa® Capsules can be taken without regards to meals.

Contraindications

Pregabalin is contraindicated in patients with known hypersensitivity to Pregabalin.

Precautions

Abrupt or rapid discontinuation of Pregabalin may produce some symptoms including insomnia, nausea, headache and diarrhoea. So Pregabalin should be tapered gradually over a minimum of 1 week rather than discontinued abruptly. Pregabalin treatment may associate with creatine kinase elevations. It should be discontinued if myopathy is diagnosed or suspected or if markedly elevated creatine kinase levels occur.

Side effects

Pregabalin is well tolerated but a few side effects like dizziness, somnolence and blurred vision may occur.

Use in pregnancy & lactation

Pregnancy: Pregabalin is a pregnancy category "C" drug. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: Pregabalin may be secreted through the breast milk like other drugs, so it should be used in nursing women only if the benefits clearly outweigh the risks.

Pediatric use

The safety and efficacy of Pregabalin in pediatric patients have not been established.

Overdosage

Overdosage of up to 8000 mg has been reported. The symptoms consist of dizziness, somnolence, blurred vision and mild diarrhoea. Pregabalin can be removed by emesis or gastric lavage.

Storage

Store at temperature not exceeding 30° C in a dry place. Protect from light.

Commercial pack

Venpa® 25 mg capsule: Each box contains 30 (3X10's) capsules in Alu-Alu blister strips.

Venpa® 50 mg capsule: Each box contains 30 (3X10's) capsules in Alu-Alu blister strips.

Venpa® 75 mg capsule: Each box contains 30 (3X10's) capsules in Alu-Alu blister strips.

For child safety: Keeping medicines out of reach



MAKS

Manufactured for

Maks Drug Limited

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