VEGAPENT CAPSULES

(Gabapentin 100 mg & 300 mg)

COMPOSITION

Each Vegapent 100 mg capsule contains Gabapentin 100 mg. Each Vegapent 300 mg capsule contains Gabapentin 300 mg. Excipients: as per approved formulation.

DESCRIPTION & PHARMACOLOGY

Gabapentin is an anticonvulsant and neuropathic pain medicine. It binds to the alpha-2-delta subunit of voltage-gated calcium channels and modulates excitatory neurotransmission. It is not a direct GABA receptor agonist.

INDICATIONS

Management of postherpetic neuralgia in adults and adjunctive treatment of partial-onset seizures, with or without secondary generalisation, in adults and children aged 3 years and above, subject to locally approved indications.

DOSAGE & ADMINISTRATION

Oral administration with or without food. Swallow capsules whole with water. Dose is individualised according to indication, clinical response and renal function.

Postherpetic neuralgia (adults): Day 1: 300 mg once; Day 2: 300 mg twice daily; Day 3: 300 mg three times daily. Thereafter titrate as needed, commonly up to 1800 mg/day in three divided doses.

ADDITIONAL DOSAGE GUIDANCE

Partial-onset seizures (12 years and older): usual initial dose 300 mg three times daily; maintenance generally 300-600 mg three times daily. The maximum interval between three daily doses should not exceed 12 hours.

Children 3-11 years: initiate at 10-15 mg/kg/day in three divided doses, then titrate under specialist supervision. Recommended maintenance dosing depends on age and weight; suitable dosage forms may be needed.

RENAL IMPAIRMENT & ELDERLY

Gabapentin is eliminated mainly unchanged by the kidneys. Reduce dose and/or dosing frequency according to creatinine clearance. Haemodialysis patients require a specific regimen. Elderly patients may require adjustment based on renal function.

DISCONTINUATION

Do not stop suddenly. When reducing or discontinuing treatment, taper gradually over at least one week, or longer as clinically appropriate, to reduce withdrawal symptoms and risk of seizures.

CONTRAINDICATIONS

Known hypersensitivity to gabapentin or any capsule ingredient.

PAEDIATRIC PRECAUTIONS

Monitor children receiving gabapentin for behavioural changes including hostility, emotional lability, hyperactivity and concentration difficulties.

WARNINGS & PRECAUTIONS

Respiratory depression may occur, especially with opioids, other central nervous system depressants, underlying respiratory disease or in elderly patients. Monitor for unusual sleepiness or slowed breathing.

Dizziness, somnolence and impaired coordination can affect driving and machinery operation. Monitor for suicidal thoughts, mood or behavioural changes. Serious hypersensitivity including DRESS, anaphylaxis and angioedema may occur; seek immediate medical attention for rash with fever, facial swelling or breathing difficulty.

DRUG INTERACTIONS

Opioids including morphine and other sedatives may increase sedation and respiratory risk. Aluminium/magnesium-containing antacids reduce gabapentin absorption; administer gabapentin at least 2 hours after such antacids. Inform the prescriber about all medicines and alcohol use.

PREGNANCY & LACTATION

Use in pregnancy only after individual benefit-risk assessment. Gabapentin passes into breast milk; assess the need for treatment and monitor breastfed infants for sedation and feeding difficulties.

ADVERSE REACTIONS

Common effects include dizziness, sleepiness, fatigue, ataxia, peripheral oedema, nystagmus, tremor, nausea and visual disturbance. Serious effects include respiratory depression, severe allergic reactions and suicidal thoughts or behaviour.

OVERDOSAGE

Overdose may cause double vision, slurred speech, drowsiness, lethargy, dizziness and diarrhoea. Severe respiratory depression is possible, particularly with sedatives. Seek emergency care. Treatment is supportive; haemodialysis may be considered in selected cases.

STORAGE CONDITIONS

Store according to approved product specifications, protected from moisture and excessive heat. Keep out of reach of children. Do not use after the expiry date.

PRESENTATION

Vegapent Capsules 100 mg: pack of 10 capsules.

Vegapent Capsules 300 mg: pack of 10 capsules.

PATIENT ADVICE

Take only as prescribed. Do not share medicine or stop abruptly. Avoid driving until effects are known. Seek help for severe rash, swelling, breathing difficulty or unusual mood changes. If a dose is missed, follow prescriber advice; do not double the next dose.

THERAPEUTIC CLASS

Anticonvulsant / neuropathic pain agent. Primary medical segments: Neurology and pain management.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.