GABANET®

DESCRIPTION

GABANET is the trademark of Gabapentin, an anticonvulsant antineuralgic agent.
Each **GABANET 100, 300** and **400** Capsule contains Gabapentin 100, 300 and 400 mg, respectively.

CHEMISTRY

Gabapentin is: 1-(Aminomethyl) cyclohexaneacetic acid.

CLINICAL PHARMACOLOGY

GABANET (Gabapentin) is an anticonvulsant agent structurally related to the inhibitory CNS neurotransmitter γ-aminobutyric acid (GABA). Although Gabapentin was developed as a structural analog of GABA that would penetrate the blood-brain barrier (unlike GABA) and mimic the action of GABA at inhibitory neuronal synapses, Gabapentin has no direct GABA-mimetic action and its precise mechanism of action has not been elucidated
Gabapentin is absorbed rapidly, as the dose increases, bioavailability decreases. The entire absorbed dose is eliminated renaly as unchanged drug.

INDICATIONS

GABANET is indicated in the treatment of

- Epilepsy
  - –As monotherapy in patients with newly diagnosed seizures.
  - –As an adjunct to other anticonvulsant medications in the treatment of partial seizures with or without secondary generalization in adults and children aged 3 years of age and above.
- Diabetic peripheral neuropathic pain in adults.
- Postherpetic neuralagia in adults.

DOSAGE

Usual adult and children 12 years of age and over

- Epilepsy: Initially 300 mg 3 times daily. The dosage may be gradually increased based on clinical response. Dosages of 900 to 1800 mg daily in 3 divided doses are effective for most patients. However, dosages as high as 2400 to 3600 mg in 3 divided doses have been well tolerated.
- Postherpetic Neuralgia: 900 mg daily in 3 divided doses. The dose can subsequently be titrated up as needed for pain relief to a daily dose of 1800 mg in 3 divided doses. In clinical studies, efficacy was demonstrated over a range of doses from1800 to 3600 mg/day with comparable effects across the dose range. Additional benefit of using doses greater than 1800 mg/day was not demonstrated.
- Diabetic peripheral neuropathic pain: Initially 900 mg daily titrated to a maximum of 3600 mg daily in 3 divided doses.

Usual pediatric dose (3-12 years)

- Epilepsy: The starting dose should range from 10-15 mg/kg/day in 3 divided doses, and the effective dose reached by upward titration over a period of approximately 3 days.
  - –Ages 5 years and older: The effective dose is 25 to 35 mg/kg/day given in 3 divided doses.
  - –Ages 3 years and 4 years: The effective dose is 40 mg/kg/day given in 3 divided doses.

GABANET Dosages up to 50 mg/kg/day have been well tolerated in a long-term clinical study.

Notes:

- In case of epilepsy, Postherpetic Neuralgia and neuropathic pain in adults the dose may be titrated gradually within the first 3 days treatment to 900 mg/day as the following dose scheme:

Day 1	Once daily 1 GABANET 300mg capsule or 3 times daily 1 GABANET 100mg capsules (300mg Gabapentin/day).
Day 2	Twice daily 1 GABANET 300mg capsule or 3 times daily 2 GABANET 100mg capsules (600mg Gabapentin/day).
From Day 3 onwards	3 times daily 1 GABANET 300mg capsule or 3 times daily 3 GABANET 100mg capsules (900mg Gabapentin/day).

- When taking **GABANET** 3 times daily, the maximum time between doses should not exceed 12 hours.
- For patients ≥12 years of age and undergoing hemodialysis: 300 to 400 mg initially for patients who have never received **GABANET** then 200 to 300 mg following each four hours of hemodialysis.
- The use of **GABANET** in patients <12 years of age with compromised renal function has not been studied.
- Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and dose should be adjusted based on creatinine clearance values.
- **GABANET** may be taken with or without food.
- Usual adult and adolescent prescribing limit is 3600 mg per day.
- The duration of treatment is depending on clinical requirements. In treatment of epilepsy, normally long term therapy is required.
- Adults with renal function impairment may require a reduction in dose as follows:

Renal Function Creatinine Clearance (mL/min)	Total Daily Dose Range (mg/day)	Dose Regimen(mg)				
≥ 60	900 - 3600	300 three times daily	400 three times daily	600 three times daily	800 three times daily	1200 three times daily
> 30 - 59	400 - 1400	200 twice daily	300 twice daily	400 twice daily	500 twice daily	700 twice daily
> 15 - 29	200 - 700	200 every day	300 every day	400 every day	500 every day	700 every day
< 15	100 - 300	100 every day	125 every day	150 every day	200 every day	300 every day

ADVERSE EFFECTS

Adverse effects from Gabapentin therapy are generally mild to moderate in severity, and tend to diminish with continued use.

More frequent effects: Ataxia, nystagmus, Dizziness, fatigue, myalgia, peripheral edema, somnolence which may be dose-related, tremor, vision abnormalities, including blurred vision, and diplopia.
In pediatric patients 3 to 12 years of age: neuropsychiatric problems, including emotional lability, hostility, hyperkinesia, and thought disorders.

Less frequent effects: Amnesia, depression, irritability, or other mood or mental changes, asthenia, back pain, dryness of mouth or throat, dysarthria, frequent urination, gastrointestinal effects, including constipation, diarrhea, dyspepsia, nausea, and vomiting, headache, hypotension, impotence, insomnia, rhinitis, tinnitus, trouble in thinking, twitching, weight gain.

USE IN PREGNANCY

Gabapentin has been shown to be fetotoxic in rodents. Adequate and well-controlled studies have not been done in humans. Gabapentin should be used during pregnancy only if the benefit justifies the potential risk to the fetus. FDA Pregnancy Category C.

USE IN LACTATION

Gabapentin is secreted into human milk following oral administration. Because of the potential for serious adverse reactions to Gabapentin in nursing infants, a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the woman.

INTERFERENCE WITH CLINICAL AND LABORATORY TESTS

- Gabapentin causes a false positive result for dipstick tests for urinary protein; the sulfosalicylic acid precipitation procedure should be used to detect urinary protein.
- White blood cell counts may be decreased.

DRUG INTERACTIONS

- Gabapentin does not induce or inhibit the hepatic mixed oxidase enzymes responsible for drug metabolism. Also, it does not interfere with the metabolism of commonly coadministered antiepileptic agents.
- Antacids, especially aluminum- and magnesium-containing taken with or within 2 hours after Gabapentin reduces Gabapentin bioavailability by 20%, Gabapentin should be taken at least 2 hours after antacid.

CONTRAINDICATIONS

- Hypersensitivity to Gabapentin.
- In patients with acute pancreatitis.
- Primarily generalized seizures, such as absences.
- In patients with galactosemia (galactose intolerance) due to lactose content.

WARNINGS

Antiepileptic drugs should not be abruptly discontinued because of the possibility of increasing seizure frequency.

OVERDOSE

Symptoms of overdoses included dizziness, diplopia, dysarthria, sedation, and mild diarrhea. Acute, life-threatening toxicity has not been observed with Gabapentin overdoses of up to 49g per day. Although Gabapentin can be removed by hemodialysis, experience has shown this to be normally unnecessary. However, hemodialysis may be indicated in patients with renal impairment.

PRECAUTIONS

- Discuses alcohol use or use of other CNS depressants with physician
- Caution when driving or doing jobs requiring alertness.

HOW SUPPLIED

- Boxes of 48 blistered Capsule of **GABANET 100**.
- Boxes of 48 blistered Capsule of **GABANET 300**.
- Boxes of 48 blistered Capsule of **GABANET 400**.
- Hospital packs of different presentations.

Store according to conditions specified on the package.
Do not use after the expiry date shown on the package.

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children.

COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

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Prescribing Information Available Upon Request

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