Gavindol Tablets

Qualitative composition/Quantitative composition: Each film coated tablet contains: Gabapentin 300 mg, vitamin B1 (thiamine mononitrate) 100 mg, vitamin B12 (cyanocobalamin) 0.20 mg, excipient q.s. 1 tablet.

Excipients. - Microcrystalline cellulose, sodium starch glycolate, magnesium stearate, povidone and red II opadry 85F15238.

Pharmaceutical form: Film coated tablet.

Pharmacotherapeutic category: Antiepileptic, analgesic and antineuritic

Therapeutic indications: GAVINDOL is indicated for the prevention and treatment of neuropathy after a herpes zoster episode; as part of painful diabetic neuropathy (acute or chronic) treatment where it relieves pain and paresthesias, improving mood and quality of life. Moreover, it is used for managing other neuropathic syndromes, such as trigeminal neuralgia or traumatic nerve injury, as well as neuropathy in patients with cancer, neuropathy in patients with multiple sclerosis or with human immunodeficiency virus infection, as well as in complex regional pain syndrome, and in phantom limb syndrome.

Contraindications: Hypersensitivity to formula components or to cobalt, vitamin B_{12} should not be used in Leber's hereditary optic neuropathy.

Special warnings: In case of neuropathic pain, its safety and efficacy in patients younger than 18 years old have not been established. Cyanocobalamin therapy may mask signs of polycythemia vera. Patients previously treated with morphine may need an increase in gabapentin dose; a dose adjustment of morphine and gabapentin is recommended as well as monitoring data of central nervous system depression, such as somnolence.

Drug interactions and other forms of interaction: Thiamine may increase the effect of neuromuscular blockers; its clinical importance is unknown. The aminosalicylic acid and omeprazole reduce vitamin B12 absorption. *In vitro,* ascorbic acid may destroy important amounts of vitamin B12 and of intrinsic factor; therefore, this possibility should be considered when high doses of ascorbic acid are administered concomitantly with vitamin B12, oral route. The concomitant administration of chloramphenicol and vitamin B12 may antagonize the haematopoietic response of the vitamin. Simultaneous administration of gabapentin with antacids containing aluminium and magnesium decreases the bioavailability by 20%. It is recommended to administer gabapentin two hours after the antacid. Renal excretion of gabapentin is not affected by probenecid. Cimetidine may slightly decrease renal excretion of gabapentin, while morphine increases it.

Pregnancy and breast feeding: Do not use during pregnancy or breastfeeding.

Intake or use of other medications: Inform your physician or pharmacist if you are taking another drug.

Dosage: **Neuropathic pain in adult patients:** initial dose is one tablet every eight hours; this dose should be adjusted according to patients' response up to a maximum dose of four tablets every eight hours.

Week	Dose	Total daily dose of gabapentin (mg/day)
1	1 tablet e/8 hours	900
2	2 tablets e/8 hours	1800
3	3 tablets e/8 hours	2700
4	4 tablets e/8 hours	3600
Maintenance: Dose at which patient's response is achieved. Do not exceed maximum dose.		

In post herpetic neuralgia: the following dosage is recommended: one tablet for day one, one tablet every 12 hours for day two, and one tablet every 8 hours for day three; dose may be increased up to 1,800 mg/day, divided in three intakes. No additional benefits have been observed above 1,800 mg/day.

Dose adjustment in patients with renal failure: a dose adjustment in patients with renal failure or under haemodialysis is recommended, since gabapentin is exclusively eliminated via renal route.

Creatinine clearance (mL/min)	Total daily dose (mg/day)
80 or higher	900 – 3600
50 to 79	600 – 1800
30 to 59	300 – 900
15 to 29	150[a] – 600
< 15	150[a] – 300

[a] One tablet every other day, single dose.

Undesirable effects: Occasionally, mild diarrhoea, rash, and pruritus have been reported with cyanocobalamin therapy. The following events have been reported with gabapentin treatment:

- Cardiovascular: peripheral and facial oedema (1.7%), vasodilatation (1.1%), and hypertension.

- Dermatological: alopecia, acne, eczema, pruritus, rash, and rarely Stevens-Johnson syndrome.
- Endocrine: weight loss secondary to anorexia or weight increase related to appetite increase. Glycaemia fluctuations in diabetic patients.
- Gastrointestinal: abdominal pain, flatulence, nausea, vomit, constipation, diarrhoea, dental abnormalities, dry mouth, and gingivitis.
- Haematological: leucopoenia and purpura.
- Musculoskeletal: arthralgias, dorsalgias or back pain, myalgias, and fractures.
- Neurological: amnesia, asthenia, confusion, emotional instability, nystagmus, abnormal thoughts, involuntary movements, muscle spasm, dysarthria, insomnia, general discomfort, somnolence, jitteriness, and tremor. Fatigue (11%), dizziness (17%), and ataxia (12.5%) are the most common events, generally reported during the first days of treatment and they decrease with treatment continuation.
- Ophthalmic: blurred vision, amblyopia, diplopia, and visual field decrease.
- Genitourinary: urinary incontinence and sexual dysfunction.
- Respiratory: rhinitis, pharyngitis, and cough.

REPORT ANY UNDESIRABLE OR DISTRESSING EFFECT WHICH HAS NOT BEEN MENTIONED IN THE PACKAGE INSERT TO YOUR PHYSICIAN OR YOUR PHARMACIST.

Overdose or accidental intake, manifestations and management (antidotes): No cases of thiamine or cyanocobalamin overdose have been described. Acute toxicity signs caused by gabapentin in animals are ataxia, gasping breathing, ptosis, hypo activity or excitation. No acute toxicity, potentially fatal, has been observed with gabapentin overdoses up to 49 grams. Overdose symptoms are diplopia, speech disorders, somnolence, lethargy, and mild diarrhoea.

All patients completely recovered with supportive measures. The low level of gabapentin absorption when administered at high doses may limit drug absorption in case of overdose and, therefore, it could minimize overdose toxicity.

Although gabapentin may be eliminated by haemodialysis, it is usually not necessary, while it could be indicated in patients with severe renal failure.

Storage: store below 30°C in a dry place.

KEEP OUT OF THE REACH OF CHILDREN

Presentation: Pack of 30 tablets in blister pack of AL-AL.