SUMMARY OF PRODUCT CHARACTERISTICS
GABAPRO (Gabapentin Tablets BP 300 mg)

1. NAME OF THE MEDICINAL PRODUCT

GABAPRO (Gabapentin Tablets BP 300 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 300 mg gabapentin.

Excipients with known effect:

Contains propylene glycol (mono propylene glycol). For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Green coloured, caplet shaped, film-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Epilepsy: Adjunctive therapy for partial seizures with and without secondary generalisation in adults and children aged ≥6 years. Monotherapy for partial seizures with and without secondary generalisation in adults and adolescents aged ≥12 years.

Peripheral neuropathic pain: Treatment of peripheral neuropathic pain such as painful diabetic neuropathy and post-herpetic neuralgia in adults.

4.2 Posology and method of administration

Adults and adolescents (≥12 years)

Epilepsy and peripheral neuropathic pain: Initiate by titrating the dose as described in Table 1, or by administering 300 mg three times daily on Day 1. The dose can be increased in 300 mg/day increments every 2–3 days up to a maximum of 3,600 mg/day. The total daily dose should be divided into three single doses; the maximum interval between doses should not exceed 12 hours.

Table 1: Dose titration schedule:

Day 1	Day 2	Day 3
300 mg once daily	300 mg twice daily	300 mg three times daily

Children aged 6–12 years (epilepsy only)

Starting dose: 10–15 mg/kg/day titrated upward over approximately 3 days to an effective dose of 25–35 mg/kg/day in three divided doses. Maximum time interval between doses should not exceed 12 hours.

Discontinuation

Discontinue gradually over a minimum of 1 week, independent of the indication.

Renal impairment

Creatinine Clearance (ml/min)	Total Daily Dose (mg/day)
>79	900–3,600 mg/day (usual dose)
50–79	600–1,800 mg/day
30–49	300–900 mg/day
15–29	150–600 mg/day
<15	150–300 mg/day

For patients on haemodialysis: loading dose of 300–400 mg followed by 200–300 mg after each 4-hour session. No treatment on dialysis-free days.

Method of administration

Oral use. Can be given with or without food; swallow whole with sufficient fluid.

4.3 Contraindications

- Hypersensitivity to gabapentin or to any excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Severe cutaneous adverse reactions (SCARs)

SJS, TEN and DRESS, which can be life-threatening or fatal, have been reported. Patients must be advised of signs and symptoms and monitored closely. If signs appear, gabapentin must be immediately withdrawn and must not be restarted if the patient has developed SJS, TEN or DRESS.

Anaphylaxis

Gabapentin can cause anaphylaxis (difficulty breathing, swelling of lips, throat and tongue, hypotension). Patients must discontinue gabapentin and seek immediate medical care.

Suicidal ideation and behaviour

Reported in patients treated with antiepileptic agents. Monitor patients for signs of suicidal ideation and behaviour. Patients and caregivers should be advised to seek medical advice if such signs emerge.

Respiratory depression

Gabapentin has been associated with severe respiratory depression. Patients with compromised respiratory function, those on CNS depressants, and the elderly are at higher risk. Dose adjustments may be necessary.

Concomitant use with opioids

Co-administration with opioids may result in respiratory depression, somnolence, sedation and increased risk of opioid-related death. The dose of gabapentin or opioids should be reduced appropriately.

Abuse, misuse and dependence

Gabapentin can cause drug dependence at therapeutic doses. Patients with a history of substance abuse are at higher risk. Evaluate risk before prescribing and monitor for drug-seeking behaviour and dose escalation.

Withdrawal symptoms

Withdrawal symptoms (anxiety, insomnia, nausea, sweating, tremor) may occur within 48 hours of discontinuation. Discontinue gradually over a minimum of 1 week.

Acute pancreatitis

If a patient develops acute pancreatitis, discontinuation of gabapentin should be considered.

Propylene glycol content

This medicinal product contains propylene glycol (mono propylene glycol). Propylene glycol may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

Opioids (morphine, tramadol):

May result in respiratory depression, somnolence and increased risk of opioid-related death. Dose adjustment of gabapentin or opioids is recommended.

Antiepileptics (phenobarbital, phenytoin, valproic acid, carbamazepine):

No pharmacokinetic interactions with gabapentin have been observed.

Antacids (aluminium/magnesium):

Reduce gabapentin bioavailability by up to 24%. Take gabapentin at least 2 hours after antacid administration.

Oral contraceptives:

Co-administration does not affect pharmacokinetics of either component.

4.6 Fertility, pregnancy and lactation

Pregnancy

The risk of birth defects is increased 2–3-fold in offspring of mothers treated with antiepileptic drugs. Gabapentin crosses the placenta. Animal studies have shown reproductive toxicity. Gabapentin should not be used during pregnancy unless the benefit to the mother clearly outweighs the risk to the foetus. Do not discontinue antiepileptic therapy suddenly.

Breast-feeding
Gabapentin is excreted in human milk. Use in breast-feeding mothers only if benefits clearly outweigh risks. Neonatal withdrawal syndrome has been reported; newborns should be monitored carefully.

Fertility
No effect on fertility in animal studies.

4.7 Effects on ability to drive and use machines
Gabapentin may have minor to moderate influence on the ability to drive and use machines. Drowsiness, dizziness and related symptoms may occur, particularly at the start of treatment and after dose increases.

4.8 Undesirable effects
Summary of the safety profile
Most common adverse reactions: somnolence, dizziness, ataxia and fatigue.

Tabulated list of adverse reactions
Frequencies: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); not known.

System Organ Class	Very Common	Common	Uncommon / Rare / Not Known
Infections	Viral infection	Pneumonia, respiratory infection, UTI, otitis media	
Blood disorders		Leukopenia	Thrombocytopenia (not known)
Immune system			Anaphylaxis; hypersensitivity/DRESS (not known); allergic reactions (uncommon)
Metabolism		Anorexia, increased appetite	Hyperglycaemia (uncommon); hypoglycaemia (rare); hyponatraemia (not known)
Psychiatric		Hostility, confusion, depression, anxiety	Agitation (uncommon); hallucinations (not known)
Nervous system	Somnolence, dizziness, ataxia	Convulsions, tremor, insomnia, headache, paraesthesia, nystagmus	Hypokinesia (uncommon); loss of consciousness (rare); other movement disorders (not known)
Eye disorders		Visual disturbances (amblyopia, diplopia)	
Ear and labyrinth		Vertigo	Tinnitus (not known)
Respiratory		Dyspnoea, bronchitis, cough, rhinitis	Respiratory depression (rare)
Gastrointestinal		Vomiting, nausea, diarrhoea, abdominal pain, dyspepsia, constipation, dry mouth, flatulence	Dysphagia (uncommon); pancreatitis (not known)
Hepatobiliary			Hepatitis, jaundice (not known)
Skin		Facial oedema, rash, pruritus, acne	SJS, angioedema, DRESS, alopecia (not known)
Musculoskeletal		Arthralgia, myalgia, back pain, twitching	Rhabdomyolysis, myoclonus (not known)
Reproductive		Impotence	Gynaecomastia, sexual dysfunction (not known)

System Organ Class	Very Common	Common	Uncommon / Rare / Not Known
General	Fatigue, fever	Peripheral oedema, abnormal gait, asthenia, pain, malaise	Generalised oedema (uncommon); withdrawal reactions, sudden unexplained death (not known)

After discontinuation, withdrawal symptoms (anxiety, insomnia, nausea, sweating, tremor) may occur within 48 hours. The patient should be informed about this at the start of treatment.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose
Acute, life-threatening toxicity not observed at overdoses up to 49 grams. Symptoms include dizziness, loss of consciousness, diplopia, slurred speech, drowsiness and mild diarrhoea. All patients recovered with supportive care. Gabapentin can be removed by haemodialysis; this may be indicated in patients with severe renal impairment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Anticonvulsants. ATC Code: N03AX12.

Mechanism of action: Gabapentin binds with high affinity to the α2δ (alpha-2-delta) subunit of voltage-gated calcium channels. Evidence from preclinical models suggests pharmacological activity is mediated via reduction in release of excitatory neurotransmitters, which may underlie both anticonvulsant and analgesic activity. Gabapentin does not act at GABAA or GABAB receptors and does not alter GABA metabolism.

5.2 Pharmacokinetic properties
Absorption: Peak plasma concentrations 2–3 hours after oral administration. Absolute bioavailability of a 300 mg capsule approximately 60%; decreases with increasing dose (non-linear). Food has no clinically significant effect.

Distribution: Not bound to plasma proteins. Volume of distribution 57.7 litres. CSF concentrations approximately 20% of steady-state trough plasma concentrations.

Biotransformation: No evidence of gabapentin metabolism in humans.

Elimination: Eliminated unchanged solely by renal excretion. Half-life 5–7 hours, independent of dose. Clearance directly proportional to creatinine clearance. Removed by haemodialysis.

5.3 Preclinical safety data
Carcinogenicity: A statistically significant increase in pancreatic acinar cell tumours in male rats at 2,000 mg/kg/day only (10× human Cmax); low-grade malignancies that did not affect survival. Relevance to human carcinogenic risk is unclear.

Mutagenesis: Gabapentin demonstrated no genotoxic potential in standard assays.

Fertility/teratogenesis: No adverse effects on fertility at doses up to 2,000 mg/kg/day in rats. Did not increase malformation incidence in mice, rats or rabbits.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
The following excipients are present in the film-coated tablet:

No.	Excipient	Specification
1	Maize starch	BP
2	Microcrystalline cellulose	BP
3	Povidone (PVP K-30)	BP

No.	Excipient	Specification
4	Isopropyl alcohol	BP
5	Purified talc	BP
6	Magnesium stearate	BP
7	Colloidal anhydrous silica	BP
8	Crospovidone	BP
9	Hydroxypropylmethylcellulose (HPMC)	BP
10	Purified water	BP
11	Titanium dioxide	BP
12	Green colour coat	IH
13	Mono propylene glycol (excipient with known effect)	BP

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store at a temperature not exceeding 30°C. Protect from light and moisture. Keep out of the reach and sight of children.

6.5 Nature and contents of container
1 ALU-ALU blister of 10 tablets; 3 such blisters packed in printed carton with package insert. Pack size: 30 tablets.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
PROMED PHARMACEUTICALS LTD

P.O. Box 22953-00100, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)
H2025/CTD12672/26903

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION
03.11.2025

10. DATE OF REVISION OF THE TEXT
03.11.2025