1.4.1

Prescribing Information (Summary of Product Characteristics)

1.4.1.1 Name of the medicinal Product

Gabapentin Capsules USP 300 mg

1.4.1.1.1 Strength

300 mg/Capsule

1.4.1.1.2 Pharmaceutical Form

Gabapentin Capsules USP 300 mg

1.4.1.2 Qualitative and Quantitative Composition

1.4.1.2.1 Qualitative declaration

Gabapentin USP

1.4.1.2.2 Quantitative declaration

Sr. No.	Ingredients	Specification	Standard Quantity/Capsule (mg)	Reason for Inclusion
01.	Gabapentin	USP	300.000	Antiepileptic Agent
02.	Pregelatinized Starch (Starch 1500)	BP	67.480	Diluent
03.	Maize Starch	BP	13.070	Diluent
04.	Purified Talc	BP	7.500	Glidant
05.	Magnesium Stearate	BP	1.950	Lubricant
06.	Pink/White Size "0" Hard Gelatin Empty Capsule	In-House	1.000 Unit	Empty capsule shell

1.4.1.3 Pharmaceutical Form

Oral Capsule

Pink / white coloured, capsule size "0" hard gelatin capsule, containing white colour granular powder.

1.4.1.4 Clinical Particulars

1.4.1.4.1 Therapeutic Indications

Gabapentin Capsule is indicated for treatment of peripheral neuropathic pain such as painful diabetic neuropathy and post-herpetic neuralgia in adults, as adjunctive therapy in treatment of partial onset seizures, with and without secondary generalization, in adults and pediatrics patients 6 years and older with epilepsy and as monotherapy in treatment of partial seizures with and without secondary generalization in adults and adolescents aged 12 years and above.

1.4.1.4.2 Posology and Method of Administration

Postherpetic Neuralgia and peripheral neuropathic pain

Adults: Initiated Gabapentin on Day 1 as single 300 mg dose, on Day 2 as 600 mg/day (300 mg two times a day), and on Day 3 as 900 mg/day (300 mg three times a day). Dose can be up titrated as needed for pain relief to a dose of 1800 mg/day (600 mg three times a day).

Epilepsy with partial onset seizures

Patients 12 years of age and above: starting dose of Gabapentin is 300 mg three times a day. The recommended maintainence dose of Gabapentin is 300 mg to 600 mg three times a day. Dosages up to 2400 mg/day have been well tolerated in long term clinical studies.

Pediatric patients aged 3 to 11 years: Starting dose range is 10 mg/kg/day to 15 mg/kg/day given in three divided doses, and recommended maintenance dose reached by upward titration over a period of approximately 3 days. Recommended age, dose up to 50 mg/kg/day have been well tolerated in long term clinical study.

Maximum time interval between doses should not exceed 12 hours.

Dosage adjustment for renal impairment or hemodialysis in patients of 12 years & older:

For creatinine clearance < 30 to 59 ml/min, total daily dose is 400 to 1400 mg/day individed dose.

For creatinine clearance > 15 to 29 ml/min, total daily dose is 200 to 700 mg/day.

For creatinine clearance for 15 ml/min, total daily dose is 100 to 300 mg/day.

1.4.1.4.3 Contraindications

In patients with history of hypersensitivity to Gabapentin or to any of excipients of this product.

1.4.1.4.4 Special Warnings and Special Precautions for Use

Gabapentin should not abruptly discontinued because of possibility of increasing seizure frequency as it may precipitate status epilepticus.

Gabapentin may increase the risk of suicidal thoughts or behavior in patients. Patients treated with Gabapentin for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior and/or any unususal changes in mood or behavior as early as one week after starting the treatment.

Gabapentin use in pediatric patients with epilepsy 3-12 years of age is associated with occurrence of CNS related adverse reactions such as emotional lability (primarily behavioral problems), hostility including aggressive behvaiours, thought disorder, including concentration problems and changes in school performance and hyperkinesia (primarily restlessness and hyperactivity).

When prescribing gabapentin carefully evaluate patients for a history of drug abuse and observe them for signs and symptoms of gabapentin misuse or abuse.

Use gabapentin with cautions as drug reaction with eosinophilla and systemic symptoms (DRESS), a multiogram hypersensitivity with fever, rash or lymphadenopathy has occurred.

Gabapentin can cause anaphylaxis and angioedema after first dose or at any time during treatment.

Gabapentin may cause significant driving impairment due to somnolence and dizziness. Patients should be carefully observed for signs of CNS depression, such as somnolence and sedation, when Gabapentin is used with other drugs with sedative properties because of potential synergy.

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

Pregnancy: Gabapentin should be used during pregnancy only if potential benefit justifies the potential risk to fetus.

Lactation: Gabapentin is secreted in to human milk causing exposure to nursed infant. Use in woman who are nursing only if benefits clearly outweigh risks.

1.4.1.4.5 Interaction with other medicinal products and other forms of interaction

No interaction between gabapentin and phenobarbital, phenytoin, valproic acid or carbamazepoine has been observed

Co-administration of Gabapentin with Hydrocodone decreses hydrocodone exposure.

Co-administration of Gabapentin with morphine may cause signs of CNS depression, such as somnolence, sedation and respiratory depression.

Concomitant use of magnesium and aluminum hydroxides antacid with gabapentin reduces gabapentin bioavailability by about 20%.

1.4.1.4.6 Pregnancy and Lactation

Pregnancy: Gabapentin should be used during pregnancy only if potential benefit justifies the potential risk to fetus.

Lactation: Gabapentin is secreted in to human milk causing exposure to nursed infant. Use in woman who are nursing only if benefits clearly outweigh risks

1.4.1.4.7 Effects on ability to Drive and use Machines

Not applicable

1.4.1.4.8 Undesirable effect

Body as whole: Asthenia, fever, fatigue, infection, accidental injury, fatigue, increased weight, back pain, peripheral edema.

Cardiovascular: Vasodilatation

Gastrointestinal system: Diarrhea, dry mouth, constipation, nausea, vomiting, dyspepsia, dental abnormalities.

Metabolic and nutritional disorder: Peripheral edema, weight gain, hyperglycemia.

Nervous System: Dizziness, somnolence, ataxia, abnormal thinking, abnormal gait, incoordination, nystagmus, tremor, dysanhria, amnesia, depression, hostility, emotional liability, hyperkinesia.

Respiratory System: Pharyngitis, coughing, bronchitis, respiratory infection.

Skin and appendages: Abrasion

Eye disorder: Amblyopia, conjunctivitis, diplopia, otitis media.

Urogenital System: Impotence

1.4.1.4.9 Overdose

Symptoms: Double vision, slurred speech, drowsiness, lethargy, coma and diarrhea.

Treatment: Supponive care is recommended. Gabapentin can be removed by hemodialysis & may be indicated by patient's

clinical state or in patients with significant renal impairment.

1.4.1.5 Pharmacological Properties

1.4.1.5.1 Pharmacodynamics Properties

Pharmacological activity of gabapentin may be mediated via binding to α20δ through a reduction in release of excitatory neurotransmitters in CNS regions. Such activity may underlie gabapentin's anti-seizure activity. All pharmacological actions following gabapentin administration are due to activity of parent compound. Analgesic activities of gabapentin may occur in the spinal cord as well as at higher brain centres through interactions with descending pain inhibitory pathways.

1.4.1.5.2 Pharmacokinetic Properties

Oral gabapentin bioavailability is not dose proportional. As dose is increased, bioavailability decreases. Bioavailability of gabapentin is approximately 60%, 47%, 34%, 33%, and 27% following 900, 1200, 2400, 3600, and 4800 mg/day given in 3 divided doses, respectively. Less than 3% of gabapentin bound to plasma protein & volume of distribution equal to 57.7litres. In epilepsy patients, steady-state predose concentrations of gabapentin in cerebrospinal flu id is approximately 20% of corresponding plasma concentrations. Gabapentin is not appreciably metabolized in humans & eliminated unchanged from systemic circulation by renal excretion with elimination half-life is 5 to 7 hours. Gabapentin elimination rate constant, plasma clearance, and renal clearance are directly proportional to creatinine clearance. In elderly patients, and in patients with impaired renal function, gabapentin plasma clearance is reduced.

1.4.1.5.3 Preclinical Safety Data

Not known.

1.4.1.6 Pharmaceutical Particulars

1.4.1.6.1 List of Excipients

Microcrystalline Cellulose BP (Plain)

Hydroxy Propyl Cellulose (Klucel-LF) USP-NF

Maize starch BP

Sodium Starch glycolate BP

Magnesium Stearate BP

Opadry white YS-1-7040 IHS

Purified water BP

1.4.1.6.2 Incompatibilities

Not applicable

1.4.1.6.3 Shelf Life

36 Months

1.4.1.6.4 Special Precautions for Storage

Do not store above 30°C. Protect from light.

1.4.1.6.5 Nature and Contents of Container

10 Tablets are packed in Alu-PVDC pack, Such 1 Blister are packed in a printed carton with packing insert.

1.4.1.6.6 Special precaution for disposal and other handling

No special requirements for disposal.

1.4.1.7 Marketing Authorization Holder and Manufacturing Site Addresses

1.4.1.7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Taluka: Kalol,

District: Gandhinagar Gujarat, India.

Telephone no.: +91-79-41078096

Fax: +91-79-41078062

E-mail: hiren@lincolnpharma.com;

Web site: www.lincolnpharma.com

1.4.1.7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
E-mail: hiren@lincolnpharma.com;
Web site: www.lincolnpharma.com

1.4.1.8 Marketing Authorization Number

To be included after obtaining first registration.

1.4.1.9 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

1.4.1.10 Date of Revision of the Text

1.4.1.11 Dosimetry (If Applicable)

Not Applicable

1.4.1.12 Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable