GABAPENTIN CAPSULES USP
GABALIN 300

POM

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

COMPOSITION:
Each hard gelatin capsule contains:
Gabapentin USP 300 mg
Excipients Q.S.
Approved colours used in capsule shell

Excipients:
Pregelatinized Starch (Starch 1500), Maize Starch, Purified Talc, Magnesium Stearate, Capsule Shell Pink/white size "0".

PHARMACOLOGICAL CLASSIFICATION:
Antiepileptic

PHARMACOLOGICAL ACTION:
Pharmacological activity of gabapentin may be mediated via binding to α2δ 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 centers through interactions with descending pain inhibitory pathways
Pharmacokinetic:
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 57.7 litres. In epilepsy patients, steady-state predose concentrations of gabapentin in cerebrospinal fluid 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.

INDICATIONS:
Gabapentin capsules 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 pediatric 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.

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

SPECIAL PRECAUTIONS AND WARNING:
Gabapentin should not be 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 unusual 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 behaviors, thought disorder, including concentration problems and change 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 caution as drug reaction with eosinophilia and systemic symptoms (DRESS), a multiorgan 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 into human milk causing exposure to nursed infant. Use in women who are nursing only if

benefits clearly outweigh risks.

DOSAGE AND DIRECTIONS FOR USE:
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 maintenance 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 maintenance dose of gabapentin is 40 mg/kg/day for 3 to 4 years of age & 25 mg/kg/day to 35 mg/kg/day for 5 to 11 years of age. Dosages 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 59ml/min, total daily dose is 400 to 1400mg/day in divided dose.
For creatinine clearance >15 to 29ml/min, total daily dose is 200 to 700mg/day.
For creatinine clearance of 15ml/min, total daily dose is 100 to 300mg/day.

ADVERSE EFFECTS:
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, dysarthria, 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

DRUG INTERACTIONS:
No interaction between gabapentin and phenobarbital, phenytoin, valproic acid or carbamazepine has been observed
Coadministration of Gabapentin with hydrocodone decreases hydrocodone exposure.
Coadministration 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%.

OVERDOSAGE:
Symptoms: Double vision, slurred speech, drowsiness, lethargy, coma and diarrhea.
Treatment: Supportive care is recommended. Gabapentin can be removed by hemodialysis & may be indicated by patient's clinical state or in patients with significant renal impairment.

PRESENTATION:
Blister Pack.

STORAGE INSTRUCTIONS:
Do not store above 30°C. Protect from light and moisture.

Manufactured by :
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