SPMC
GABAPENTIN CAPSULES USP 300 mg

PRESENTATION:
Gabapentin capsules USP 300 mg, Gabapentin capsules USP 300 mg, packs of 1000 capsules
Each capsule of pink cap printed with "SPMC" logo and pink body printed with letters "SPMC" circularly rectified in edible ink each contains 300 mg of Gabapentin.

ACTION:
Gabapentin is structurally related to neurotransmitter GABA. It does not bind to GABAA or GABAB receptors nor influence the synthesis or uptake of GABA. It binds with high affinity to the α-2-δ-1 subunit of voltage-gated Ca channels, thereby modulating the release of excitatory neurotransmitters which participate in epileptogenesis and nociception.

INDICATIONS AND DOSE:
Adjunctive treatment of focal seizures with or without secondary generalisation
Child 6–11 years: 10 mg/kg once daily (max. per dose 300 mg) on day 1, then 10 mg/kg twice daily (max. per dose 300 mg) on day 2, then 10 mg/kg 3 times a day (max. per dose 300 mg) on day 3; usual dose 25–35 mg/kg daily in 3 divided doses, some children may not tolerate daily increments; longer intervals (up to weekly) may be more appropriate, daily dose maximum to be given in 3 divided doses; maximum70 mg/kg per day
Child 12–17 years: Initially 300 mg once daily on day 1, then 300 mg twice daily on day 2, then 300 mg 3 times a day on day 3, alternatively initially 300 mg 3 times a day on day 1, then increased in steps of 300 mg every 2–3 days in 3 divided doses, adjusted according to response; usual dose 0.9–3.6 g daily in 3 divided doses (max. per dose 1.6 g 3 times a day), some children may not tolerate daily increments; longer intervals (up to weekly) may be more appropriate
Adult: Initially 300 mg once daily on day 1, then
300 mg twice daily on day 2, then 300 mg 3 times a day on day 3, alternatively initially 300 mg 3 times a day on day 1, then increased in steps of 300 mg every 2–3 days in 3 divided doses, adjusted according to response; usual dose 0.9–3.6 g daily in 3 divided doses (max. per dose 1.6 g 3 times a day))

Monotherapy for focal seizures with or without secondary Generalization
Child 12–17 years: Initially 300 mg once daily on day 1, Then 300 mg twice daily on day 2, then 300 mg 3 times A day on day 3, alternatively initially 300 mg 3 times a Day on day 1, then increased in steps of 300 mg every 2–3 days in 3 divided doses, adjusted according to response; usual dose 0.9–3.6 g daily in 3 divided doses (Max. per dose 1.6 g 3 times a day), some children may Not tolerate daily increments; longer intervals (up to weekly) may be more appropriate
Adult: Initially 300 mg once daily on day 1, then 300 mg twice daily on day 2, then 300 mg 3 times a day on day 3, alternatively initially 300 mg 3 times a day on Day 1, then increased in steps of 300 mg every 2–3 days In 3 divided doses, adjusted according to response; usual dose 0.9–3.6 g daily in 3 divided doses (max. per Dose 1.6 g 3 times a day)
Peripheral neuropathic pain
***Adult*:** Initially 300 mg once daily on day 1, then 300 mg twice daily on day 2, then 300 mg 3 times a day on day 3, alternatively initially 300 mg 3 times a day on Day 1, then increased in steps of 300 mg every 2–3 days in 3 divided doses, adjusted according to response; Maximum 3.6 g per day
Menopausal symptoms, particularly hot flushes, in women with breast cancer
Adult: 300 mg 3 times a day, initial dose should be lower and titrated up over three days
Oscillopsia in multiple sclerosis
Adult: Initially 300 mg once daily, then increased in steps of 300 mg, every 4–7 days, adjusted according to response; usual maximum 900mg 3 times a day.
Spasticity in multiple sclerosis
Adult: Initially 300 mg once daily for 1–2 weeks, then 300 mg twice daily for 1–2 weeks, then 300 mg 3 times a day for 1–2 weeks, alternatively initially 100 mg 3 times a day, then increased in steps of 100 mg 3 times a day, every 1–2 weeks, adjusted according to response; usual maximum 900 mg 3 times a day.

CAUTIONS:
Diabetes mellitus. Elderly. High doses of oral Solution in adolescents and adults with low body-weight. History of psychotic illness. Mixed seizures (including Absences)

SPECIAL PRECAUTIONS:
Patients with mixed seizures including absences, compromised respiratory function, respiratory or neurological disease, history of substance abuse (e.g. alcohol, benzodiazepines, cannabis, cocaine, opioids). Concomitant use with opioids. Avoid abrupt withdrawal. Renal impairment. Children and elderly. Pregnancy and lactation.

SIDE EFFECTS:
Common or very common
Anxiety . appetite abnormal arthralgia . asthenia . behaviour abnormal. confusion constipation . cough . depression . diarrhoea . dizziness drowsiness. dry mouth. dysarthria . dyspnoea. emotional lability . flatulence . gait abnormal. Gastrointestinal discomfort . headache . hypertension . increased risk of infection . insomnia . leucopenia . malaise .movement disorders . muscle complaints . nausea .nystagmus . oedema . pain . reflexes abnormal. seizure (in children) . sensation abnormal. sexual dysfunction . skin reactions . thinking abnormal . tooth disorder . tremor . vasodilation . vertigo. visual impairment . vomiting
Uncommon Cognitive impairment. palpitations
Frequency not known Acute kidney injury. alopecia . angioedema . breast enlargement. drug use disorders gynaecomastia. hallucination . hepatic disorders hyponatraemia. pancreatitis . rhabdomyolysis . severe cutaneous adverse reactions (SCARs). suicidal behaviours .thrombocytopenia. tinnitus . urinary incontinence

RENAL IMPAIRMENT:
Dose adjustments In adults Manufacturer advises reduce dose to 600–1800 mg daily in 3 divided doses if creatinine clearance 50–79 ml/minute. Manufacturer advises reduce dose to 300–900 mg daily in 3 divided doses if creatinine clearance 30–49 ml/minute. Manufacturer advises reduce dose to 150–600 mg daily in 3 divided doses if creatinine clearance 15–29 ml/minute (150 mg daily dose to be given as 300 mg in 3 divided doses on alternate days). Manufacturer advises reduce dose to 150–300 mg daily in 3 divided doses if creatinine clearance is less than 15 ml/minute (150 mg daily dose to be given as 300 mg in 3 divided doses on alternate days)—further dose reductions may be required in proportion to creatinine clearance, consult product literature.
Dose adjustments in children Reduce dose if estimated glomerular filtration rate less than 80 ml/minute/1.73m2; consult product literature.

PREGNANCY:
The dose should be monitored carefully during pregnancy and after birth, and adjustments made on a clinical basis.

BREAST FEEDING:
Present in milk—been advised use only if potential benefit outweighs risk.

IMPORTANT SAFETY INFORMATION:
Gabapentin has been associated with a rare risk of severe respiratory depression even without concomitant opioid medicines. Patients with compromised respiratory function, respiratory or neurological disease, renal impairment, concomitant use of central nervous system (CNS) depressants, and elderly people might be at higher risk of experiencing severe respiratory depression and dose adjustments may be necessary in these patients.

MONITORING REQUIREMENTS:
Monitor for signs of Gabapentin abuse.

PATIENT COUNSELING INFORMATION:
This drug may cause dizziness and drowsiness, if affected, do not drive or operate machinery.

DRUG INTERACTION:
Bioavailability of Gabapentin increased by Morphine. Absorption of Gabapentin reduced by antacids. Anticonvulsant effect of antiepileptic possibly antagonized by MAOIs and tricyclic related antidepressants; anticonvulsant effect of antiepileptic antagonized by SSRIs and tricyclics; avoid concomitant use of antiepileptic with St John's wort. Anticonvulsant effect of antiepileptic antagonized by mefloquine. Anticonvulsant effect of antiepileptic antagonized by antipsychotics. Possible increased risk of convulsions when antiepileptic given with orlistat.

FOOD INTERACTION:
May enhance CNS depressant effect of alcohol.

OVERDOSAGE:
Symptoms: Dizziness, drowsiness, double vision, slurred speech, mild diarrhoea, lethargy, and loss of consciousness. Management: Symptomatic and supportive treatment. May consider haemodialysis in patients with severe renal impairment

STORAGE:
Keep tightly closed in a cool & dry place. Store below 30°C in the original package in order to protect from moisture & Light.

Keep all medicines away from the reach of children

Manufactured by:
State Pharmaceuticals Manufacturing Corporation
No. 11, Sir John Kotalawala Mawatha, Kandawala Estate,
Ratmalana, Sri Lanka.