SPMC
TRAMADOL CAPSULES IP 50 mg

PRESENTATION:
Tramadol Capsules IP 50 mg:
Bulk Packs containing 100 capsules & Blister pack containing 100 capsules. (10x10'S)

Each capsule is light orange body & greenish brown cap size no.2 printed with SPMC logo & "SPMC" letters on cap & body. Each capsule Contains **Tramadol hydrochloride IP 50 mg.**

INDICATIONS AND DOSE:
Moderate to severe acute pain
Child 12–17 years: Initially 100 mg, then 50–100 mg every 4–6 hours; Usual maximum 400 mg/24 hours
Adult: Initially 100 mg, then 50–100 mg every 4–6 hours; Usual maximum 400 mg/24 hours
Moderate to severe chronic pain
Child 12–17 years: Initially 50 mg, then, adjusted according to response; Usual maximum 400 mg/24 hours
Adult: Initially 50 mg, then, adjusted according to response; Usual maximum 400 mg/24 hours

CONTRA INDICATIONS:
Acute intoxication with alcohol, analgesics, hypnotics, opioids. not suitable for narcotic withdrawal treatment. uncontrolled epilepsy.

CAUTIONS:
Excessive bronchial secretions. history of epilepsy—use tramadol only if compelling reasons. impaired consciousness. not suitable as a substitute in opioid-dependent patients. not suitable in some types of general anesthesia. postoperative use (in children). susceptibility to seizures—use tramadol only if compelling reasons. variation in metabolism. may mask the symptoms of gastric cancer (in adults). Patients at risk of osteoporosis.

SIDE EFFECTS:
GENERAL SIDE-EFFECTS
Common or very common -Fatigue
Rare or very rare -Dyspnoea. epileptiform seizure. respiratory disorders. sleep disorders. vision blurred
Frequency not known - Asthma exacerbated. hypoglycaemia

SPECIFIC SIDE-EFFECTS
Uncommon
With parenteral use Circulatory collapse. Gastrointestinal discomfort
Rare or very rare
With parenteral use Angioedema. appetite change. behaviour abnormal. cognitive disorder. dysuria. hypersensitivity. mood altered. movement disorders. muscle weakness. perception disorders. Psychiatric disorder. sensation abnormal
Frequency not known
With oral use Anxiety. blood disorder. Gastrointestinal disorder. hyperkinesia. hypertension. paraesthesia. syncope. tremor. urinary disorder

USE IN PREGNANCY:
Embryotoxic in animal studies, advise avoid.

BREAST FEEDING:
Amount probably too small to be harmful, but advise avoid.

HEPATIC IMPAIRMENT:
Caution (avoid for oral drops) in severe impairment.

RENAL IMPAIRMENT:
Avoid use or reduce dose; opioid effects increased and prolonged and increased cerebral sensitivity occurs. Caution (avoid for oral drops) in severe impairment.

TREATMENT CESSATION:
Manufacturer advises consider tapering the dose gradually to prevent withdrawal symptoms.

INTERACTION:
Increased risk of convulsions or serotonin syndrome with SSRI, serotonin-norepinephrine reuptake inhibitors (SNRI), TCA and other seizure threshold lowering drugs (e.g., bupropion, mirtazapine, tetrahydrocannabinol). Decreased serum concentrations with carbamazepine. May potentiate the anti-depressant effect of norepinephrine, 5-HT agonists or lithium. Increased INR and ecchymoses with coumarin derivatives (e.g. Warfarin). **Potentially Fatal:** Increased risk of seizures with MAOIs.

OVERDOSAGE:
Symptoms
In principle, on intoxication with tramadol symptoms similar to those of other centrally acting analgesics (opioids) are to be expected. These include in particular miosis, vomiting, cardiovascular collapse, consciousness disorders up to coma, convulsions and respiratory depression up to respiratory arrest.

Treatment
The general emergency measures apply. Keep open the respiratory tract (aspiration), maintain respiration and circulation depending on the symptoms. The stomach is to be emptied by vomiting (conscious patient) or gastric irrigation. The antidote for respiratory depression is naloxone. In animal experiments naloxone had no effect on convulsions. In such cases diazepam should be given intravenously. Tramadol is minimally eliminated from the serum by haemo dialysis or haemo-filtration. Therefore, treatment of acute intoxication with tramadol with haemo dialysis or haemo filtration alone is not suitable for detoxification.

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

Keep all medicines away from children.

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