

PATIENT INFORMATION LEAFLET
[STROM-50] TRAMADOL CAPSULES BP 50 MG
[Tramadol Hydrochloride BP]

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

WHAT IS IN THIS LEAFLET:

1. What tramadol capsules is and what it is used for
2. Before you use tramadol capsules
3. How to use tramadol capsules
4. Possible side effects
5. How to store tramadol capsules
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1. WHAT TRAMADOL CAPSULES IS AND WHAT IT IS USED FOR

It contain active ingredient tramadol hydrochloride. It is centrally acting analgesic and active metabolite (M1) binds to μ -opiate receptors in the CNS causing inhibition of ascending pain pathways, altering the perception of and response to pain; also inhibits the reuptake of norepinephrine and serotonin, which also modifies the ascending pain pathway. It is used for the treatment of moderate to severe pain.

2. BEFORE YOU USE TRAMADOL CAPSULES

It is contraindicated in patient with known hypersensitivity to tramadol hydrochloride or to any of excipients. It is contraindicated: In acute intoxication with alcohol, hypnotics, analgesics, opioids, or psychotropic medicinal products. In patients who are receiving MAO inhibitors or who have taken them within the last 14 days. In patients with epilepsy not adequately controlled by treatment. Do not take if any of the above apply to you. If you are not sure, talk to your physician, pharmacist or nurse before having tramadol capsules.

Take special care with Tramadol capsules: Warnings and Precautions: Talk to your physician before taking tramadol capsules. Use with caution on elderly patients. **CNS depression**, which may impair physical or mental abilities; patients must be cautioned about performing tasks which require mental alertness. **Respiratory disease:** Patients with respiratory disorders (e.g., significant chronic obstructive pulmonary disease (COPD), hypoxia) may be at greater risk of respiratory depression. **Drug abuse:** Use with caution in patients with a history of drug abuse or acute alcoholism; potential for drug dependency exists. **Head trauma:** Use with extreme caution in patients with head injury, intracranial lesions, or elevated intracranial pressure may occur. **Renal impairment:** Use with caution and reduce dosage in patients with mild-to-moderate renal impairment; it should not be used in severe renal impairment $Cl_{cr} < 30$ mL/minute. **Hepatic impairment:** Use with caution and reduce dosage in patients with mild-to-moderate hepatic impairment; it should not be used in severe hepatic impairment. **Pediatric Use:** On account of their high dosage strengths, tramadol capsules are not recommended for use in children below the

age of 12 years. **Geriatric Use:** In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function and of concomitant disease or other drug therapy. In patients over 75 years of age, daily doses in excess of 300 mg are not recommended.

Using other medicines: Tell your physician if you are taking it may enhance the neuroexcitatory and/or seizure-potentiating effect of with Tricyclic Antidepressants, MAO Inhibitors and selective serotonin reuptake inhibitors. It enhance the toxic effect of other serotonin modulators. Succinylcholine; bradycardic effect of opioid analgesics (Opioid). Thiazide Diuretics enhance orthostatic hypotensive effect. Vitamin K Antagonists (e.g., warfarin. Analgesics (Opioid) may enhance the adverse/toxic effect of Desmopressin. Droperidol or hydroxyzine: May enhance the CNS depressant effect of CNS Depressants.

Using tramadol capsules with food and drink: It may be taken with or without food or as directed by physician. It is contraindicated in acute intoxication with alcohol. Patients should avoid the alcohol. **Pregnancy and breast-feeding: Pregnancy:** It should not be used during pregnancy as there is inadequate evidence available to assess the safety of tramadol in pregnant women. **Breast-feeding:** It should not be administered during breast feeding as tramadol and its metabolites have been detected in breast milk. 0.1% of the dose administered to the mother may be excreted in milk. **Driving and using machines:** Avoid driving a motor vehicle or operating machinery while taking this drug. It can cause mental alertness. **Important information about some of the ingredients: It contains:** Each hard gelatin capsules contains lactose monohydrate, patients with rare hereditary problems of galactose intolerance, total-lactase deficiency or glucose-galactose malabsorption should not take this medicine. Talk to your physician.

3. HOW TO USE TRAMADOL CAPSULES

Method of administration: For oral use only. It may be taken with or without food or as directed by physician. It should be swallowed with a glass of water. **The usual recommended doses: Adults and children over 12 years:** Usual doses are 50 to 100 mg every four to six hours. For acute pain an initial dose of 100 mg is required. For chronic painful conditions an initial dose of 50 mg is recommended. Subsequent doses should be 50 to 100 mg administered 4-6 hourly. The dose level and frequency of dosing will depend on the severity of the pain. The total daily dosage by mouth should not exceed 400 mg or as directed by the physician.

If you more tramadol capsules than you should: Symptoms of overdose includes miosis, vomiting, cardiovascular collapse, consciousness disorders up to coma, convulsions and respiratory depression up to respiratory arrest. Treatment should be symptomatic and supportive. The maintenance of the airway and cardiovascular functions. Respiratory depression may be reversed using naloxone and fits controlled with diazepam. Naloxone administration may increase the risk of seizures. **If you forget to tramadol capsules: Do** not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. POSSIBLE SIDE EFFECTS

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist. Following possible adverse reactions may include: Flushing, postural hypotension, chest pain, hypertension, peripheral edema, and vasodilation, Dizziness, headache, somnolence, insomnia, agitation, anxiety, apathy, chills, confusion, impaired coordination, depersonalization, depression, hypoesthesia, lethargy, nervousness, restlessness, malaise, fatigue, vertigo, Pruritus, dermatitis, rash. Hyperglycemia and

menopausal symptoms. Gastrointestinal: Constipation, nausea, vomiting, dyspepsia, diarrhea, anorexia, abdominal pain, weight loss, and flatulence. Genitourinary: Pelvic pain, prostatic disorder, urine abnormalities, urinary tract infection, urinary frequency, urinary retention. Neuromuscular & skeletal: Weakness, arthralgia, increased creatine phosphokinase, myalgia. Blurred vision, miosis. Bronchitis, congestion (nasal/sinus), cough, dyspnea, nasopharyngitis, pharyngitis, rhinitis, rhinorrhea, sinusitis, sneezing, sore throat, upper respiratory infection. Diaphoresis, flu-like syndrome. May aggravate. Bronchospasm in patient's sensitive to acetyl salicylic acid or other analgesics.

5. HOW TO STORE TRAMADOL CAPSULES

Keep this medicine out of the sight and reach of children. Store below 30°C. Protect from light & moisture. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. FURTHER INFORMATION

It contain active substances as tramadol hydrochloride BP. Excipients: Lactose Monohydrate, Calcium Hydrogen Phosphate (Anhydrous), Colloidal Anhydrous Silica (Aerosil), Magnesium Stearate **Pack size:** Green/green colour size "4" capsule containing white to off-white colour powder. Such 10 are blister packed and such one blister is packed in printed carton with packing insert.

Manufactured by:

Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Taluka: Kalol,

District: Gandhinagar Gujarat, India.

Phone: +91-079-41078096

Telefax: +91-79-41078062

Email: hiren@lincolnpharma.com

Website: www.lincolnpharma.com

For any information about this medicinal product, please contact the local representative of the supplier:

Lincoln Pharmaceuticals Limited Trimul Estate, Khatraj, Taluka: Kalol, District: Gandhinagar Gujarat, India. Phone: +91-079-41078096 Telefax: +91-79-41078062 Email: hiren@lincolnpharma.com Website: www.lincolnpharma.com	Abacus Pharma (A) Ltd Kigali city market, B1-R85, PO Box 4344, Kigali, Rwanda. Phone: +91-079-41078096 Telefax: +91-79-41078062 Email: abacuspharmacist@gmail.com
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