

Tramadol Hydrochloride Tablets

Tramadol 50 mg

Composition: Each uncoated tablet contains:
Tramadol Hydrochloride BP 50 mg
Excipients q.s.

Therapeutic Indications:

Treatment of moderate to severe pain.

Dosage and Method of Administration:

The dose should be adjusted to the intensity of the pain and the sensitivity of the individual patient. The lowest effective dose for analgesia should generally be selected.

Oral administration

Acute pain: An initial dose is 50–100 mg, depending on the intensity of the pain. This may be followed by doses of 50 or 100 mg 4–6 hours later, and the duration of therapy should be tailored to clinical needs. A total daily dose of 400 mg should not be exceeded, except in special clinical circumstances. Pain associated with chronic conditions: Use an initial dose of 50 mg, and subsequently adjust the dose according to the severity of the pain. The initial dose may be followed, if necessary, by 50–100 mg every 4–6 hours. The recommended doses serve as a guideline. Patients should always receive the lowest dose that provides effective pain control. The need for continued treatment should be assessed at regular intervals, as withdrawal symptoms and dependence have been reported. The tablets should be taken whole—*not* divided or chewed—with sufficient liquid, regardless of meals. Tramadol should under no circumstances be administered for longer than is absolutely necessary. If long-term pain treatment with tramadol is required—taking into account the nature and severity of the condition—careful and regular monitoring (including treatment breaks, if necessary) should be conducted to determine whether, and to what extent, further treatment is needed.

Contraindications

Tramadol is contraindicated:

- in cases of hypersensitivity to tramadol hydrochloride or to any of the excipients;
- in cases of acute intoxication with alcohol, hypnotics, analgesics, opioids, or psychotropic medications;
- in patients who are receiving MAO inhibitors or who have taken them within the last 14 days;
- in patients with epilepsy that is not adequately controlled by treatment;
- for use in the treatment of narcotic withdrawal.

Special warnings and precautions for use: Tramadol should be used with particular caution in patients dependent on opioids, patients with head injuries, shock, a reduced level of consciousness of uncertain origin, disorders of the respiratory center or function, or increased intracranial pressure. In patients sensitive to opioids, the product should be used only with caution.

Care should be taken when treating patients with respiratory depression, or if concomitant CNS-depressant medications are being administered, or if the recommended dosage is significantly exceeded, as the possibility of respiratory depression cannot be ruled out in these situations. Seizures have been reported in patients receiving tramadol at recommended dose levels. The risk may be increased when tramadol doses exceed the recommended upper daily dose limit (400 mg). Furthermore, tramadol may increase the risk of seizures in patients taking other medications that lower the seizure threshold. Patients with epilepsy or those susceptible to seizures should be treated with tramadol only if there are compelling circumstances. Tramadol has a low dependence potential. With long-term use, tolerance may develop, and psychological and physical dependence may occur. In patients with a tendency toward drug abuse or dependence, treatment with tramadol should be carried out only for short periods under strict medical supervision. Tramadol is not suitable as a substitute in opioid-dependent patients. Although it is an opioid agonist, tramadol cannot suppress morphine withdrawal symptoms. Tramadol should be used with caution in patients with hepatic or renal impairment.

Fertility, Pregnancy, and Lactation: Animal studies with tramadol have revealed effects of very high doses on organ development, ossification, and neonatal mortality. No teratogenic effects were observed. Tramadol crosses the placenta. There is inadequate evidence available regarding the safety of tramadol during human pregnancy. Therefore, tramadol should not be used in pregnant women.

Tramadol—administered before or during delivery—does not affect uterine contractility. In newborns, it may induce changes in respiratory rate, which are generally not clinically relevant. Chronic use during pregnancy may lead to neonatal withdrawal symptoms. During lactation, approximately 0.1% of the maternal dose is secreted into breast milk.

Tramadol is not recommended during breastfeeding. After a single administration of tramadol, it is generally not necessary to interrupt breastfeeding.

Effects on the ability to drive and use machines: Even when taken according to instructions, Tramadol may cause effects such as drowsiness and dizziness and, therefore, may impair the reactions of drivers and machine operators. This applies particularly in combination with alcohol and other psychotropic substances.

Undesirable Effects: Undesirable effects are classified by System Organ Class, and their frequency is classified as follows: Very common (31/100 to <1/10), uncommon (31/1,000 to <1/100), rare (31/10,000 to <1/1,000), very rare (<1/10,000), and unknown (cannot be estimated from available data). The most commonly reported adverse reactions are nausea and dizziness, both occurring in more than 10% of patients.

Overdose

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In principle, intoxication with tramadol is expected to present symptoms similar to those of other centrally acting analgesics (opioids). These include, in particular, miosis, vomiting, cardiovascular collapse, disturbances of consciousness ranging to coma, seizures, and respiratory depression ranging to respiratory arrest.

Treatment

General emergency measures apply. Maintain an open airway (suctioning), and support respiration and circulation as indicated by symptoms. The stomach should be emptied via induced vomiting (in conscious patients) or gastric lavage. The antidote for respiratory depression is naloxone. In animal studies, naloxone had no effect on seizures; in such cases, diazepam should be administered intravenously. Tramadol is minimally eliminated from the serum by hemodialysis or hemofiltration. Therefore, treating acute tramadol intoxication solely with hemodialysis or hemofiltration is not an effective method for detoxification.

Dosage: As directed by a physician.

Storage: Store below 30°C in a cool, dry place. Protect from light.

Keep out of reach of children.

Presentation: Blister pack of 10 tablets.

Manufactured by:

