

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Tramapine 50 mg capsules**  
**tramadol hydrochloride**

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor 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 doctor or pharmacist.

**In this leaflet:**

1. What Tramapine 50 mg capsules are and what they are used for
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**1. What Tramapine 50 mg Capsules are and what they are used for**

Tramapine 50 mg capsules contain the active ingredient tramadol hydrochloride, which belongs to a group of pain-relieving medicines called opioid analgesics, used for the treatment and prevention of severe pain.

**2. What you need to know before you take Tramapine 50 mg Capsules**

**Do NOT take Tramapine 50 mg capsules:**

- if you are allergic (hypersensitive) to tramadol or any of the other ingredients in the product (see *Section 6*)
- if you are allergic (hypersensitive) to other opioids
- if you have taken any medicines or alcohol that make you sleepy or less alert:
  - o including sleeping pills, analgesics or drugs that act on the nervous system such as morphine and codeine (tramadol should not be used for opioid withdrawal treatment),
- if you are taking or have recently taken (within the last two weeks) an antidepressant known as a monoamine oxidase inhibitor (MAOI)
- If you are an epileptic and your fits are not adequately controlled by treatment;
- as a substitute in drug withdrawal.

These capsules should NOT be used in children under 1 year of age.

**Take special care with Tramapine 50 mg capsules and consult your doctor if you have:**

- a dependency on opioids; tramadol should be used with caution for short periods, under strict medical supervision if you are sensitive to opioids
- suffered head injuries, increased brain pressure, shock or decreased level of consciousness e.g. from an accident
- breathing difficulties
- moderate to severe liver or kidney problems
- a history of epilepsy or are prone to seizures (fits); this medicine should only be used if considered essential by your doctor as the risk of seizures may increase
- to have a general anaesthetic. Tell the doctor or anaesthetist that you are taking these capsules
- a sugar intolerance.

Epileptic fits have been reported in patients taking tramadol at the recommended dose level. The risk may be increased when doses of tramadol exceed the recommended upper daily dose limit (400 mg).

**If you are taking these capsules long-term, there is a risk that mental or physical dependence may develop. Your doctor will monitor you regularly.** In patients with a tendency to abuse medicines or who are dependant on medicines, treatment with this medicine should only be carried for short periods and under strict medical supervision.

**Warning and precautions**

Tramadol is transformed in the liver by an enzyme. Some people have a variation of this enzyme and this can affect people in different ways. In some people, they may not get enough pain relief but other people are more likely to get serious side effects. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

**Children and adolescents**

Use in children with breathing problems

Tramadol is not recommended in children with breathing problems, since the symptoms of tramadol toxicity may be worse in these children.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription, particularly:

- MAOIs e.g. moclobemide or phenelzine for depression, selegiline for Parkinson's disease - or in the two weeks after you have stopped taking them (see *Section 2 "Do not take"*) – life-threatening interactions affecting the central nervous system, respiratory or heart function have been seen
- alcohol and other drugs that act on the central nervous system (see *section 2 "Do not take"*)
- carbamazepine (for epilepsy) which may reduce the effectiveness of tramadol
- tricyclic antidepressants and antipsychotic medicines; there may be an increased risk of epileptic fits
- cimetidine used to treat gastrointestinal disorders, such as peptic ulcers
- selective serotonin re-uptake inhibitors (SSRIs, certain antidepressants); the side effects of these can be enhanced if taken together with tramadol. You could get "serotonin syndrome", signs of which are confusion, restlessness, fever, sweating, reduced coordination, increased sensitivity to stimuli, increased reflex actions, spasms/muscle contractions and diarrhoea. If this happens to you, STOP taking the SSRI and speak to your doctor about other treatment

The risk of side effects increases:

- if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk of having a fit may increase if you take Tramapine 50 mg capsules at the same time. Your doctor will tell you whether Tramapine 50 mg Capsules is suitable for you.
- if you are taking certain antidepressants. Tramapine 50 mg Capsules may interact with these medicines and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C.
- if you are taking coumarin anticoagulants (medicines for blood thinning), e.g. warfarin, together with Tramapine 50 mg Capsules. The effect of these medicines on blood clotting may be affected and bleeding may occur.

Tramadol should be used with caution and only under medical supervision in seriously ill patients including those with breathing difficulties, excessively low blood pressure (shock), serious head injury or brain diseases that may cause elevated pressure in the skull.

**Taking Tramapine 50 mg capsules with food and drink**

These capsules can be taken with or without food. Avoid alcohol when taking this medicine.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. There is very little information regarding the safety of tramadol in human pregnancy. Therefore you should not use Tramapine 50 mg Capsules if you are pregnant. Chronic use during pregnancy may lead to withdrawal symptoms in newborns.

**Breast-feeding**

Tramadol is excreted into breast milk. For this reason, you should not take Tramapine 50 mg Capsules more than once during breast-feeding, or alternatively, if you take Tramapine 50 mg Capsules more than once, you should stop breast-feeding. Based on human experience tramadol is suggested not to influence female or male fertility.

**Driving and using machines**

Tramapine 50 mg capsules may cause drowsiness and dizziness (this can be increased by alcohol or any drug that acts on the central nervous system); do not drive or operate dangerous machinery until you know how this medicine affects you.

**Important information about some of the ingredients of Tramapine 50 mg capsules**

- Lactose - if you know you or your child have an intolerance to some sugars, talk to your doctor before taking/giving this medicine.

**3. How to take Tramapine 50 mg Capsules**

Always take this medicine exactly as your doctor has told you; you should check with him/her if you are not sure. The dosage should be adjusted to the intensity of your pain and your individual pain sensitivity. In general the lowest pain-relieving dose should be taken. These capsules can be taken at mealtimes or without food, swallowed whole (without chewing or breaking) with plenty of liquid.

Tramadol is available in several strengths – 50 mg, 100 mg, 150 mg and 200 mg. Your doctor will adjust your dose according to the severity of pain and your response. Tramadol should NOT be used longer than necessary; talk to your doctor if you need long-term pain treatment.

- **Adults and adolescents over 14 years:** depending on the severity of the pain the initial dose is 50 - 100 mg every 4-6 hours (if required), up to a maximum of 400 mg a day. For sudden severe pain an initial dose of 100 mg is usually required. For chronic pain an initial dose of 50 mg is recommended.
- **Children aged 1 - 14 years:** the dose is 1-2 mg/kg body weight every 4 - 6 hours. Your doctor will advise the dose.
- **Elderly patients:** In elderly patients (above 75 years) the excretion of tramadol may be delayed. If this applies to you, your doctor may recommend prolonging the dosage interval.
- **Children under 1 year:** this medicine is NOT recommended.
- **Severe liver or kidney disease (insufficiency)/dialysis patients:** Patients with severe liver and/or kidney insufficiency should not take Tramapine 50 mg Capsules without talking to their doctor. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

**If you are taking these capsules long-term, there is a risk that mental or physical dependence may develop. Your doctor will monitor you regularly.**

**If you take more Tramapine 50 mg capsules than you should**

If you, or someone else, have taken too much medicine, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the pack with you. *Symptoms of overdose* include: narrowing of the pupils, vomiting, seizures (fits), heart and breathing problems, altered consciousness leading to coma.

**If you forget to take Tramapine 50 mg capsules**

If you miss a dose, take one as soon as you remember, unless it is nearly time to take the next one. Take the remaining dose at the correct time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Tramapine 50 mg capsules**

Do not stop taking these capsules, even if you start feeling better; continue taking them for as long as your doctor has advised otherwise your pain may return. Early withdrawal of this medicine may cause agitation, nervousness, insomnia, abnormal muscular activity, tremor and gastro-intestinal symptoms. You should not suddenly stop taking this medicine unless your doctor tells you to. If you want to stop taking your medicine, discuss this with your doctor first, particularly if you have been taking it for a long time. Your doctor will advise you when and how to stop, which may be by lowering the dose gradually to reduce the chance of developing unnecessary side effects (withdrawal symptoms).

If you have any further questions on the use of this product, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, Tramapine 50 mg capsules may cause side effects, although not everybody gets them.

**STOP** taking these capsules and **seek medical help immediately** if you have any of the following which may be signs of a rare **allergic reaction**:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

**Very common** (affecting more than 1 in 10 users)

- dizziness
- feeling sick (nausea).

**Common** (affecting between 1 in 100 and 1 in 10 users)

- headaches, drowsiness
- vomiting, constipation, dry mouth
- sweating
- tiredness.

**Uncommon** (affecting between 1 in 1,000 and 1 in 100 users)

- heart problems (palpitations, fast heart rate, feeling faint upon standing, heart failure), especially if tramadol is given by injection, or in patients who are physically stressed
- retching (unproductive effort to vomit), bloating/pressure in the stomach, diarrhoea
- skin reactions (e.g. itching, rash, hives)
- flushing - skin redness.

**Rare** (affecting between 1 in 10,000 and 1 in 1,000 users)

- slow heart rate, increased blood pressure
- epileptic fits
- changes in appetite, numbness/tingling "pins and needles", tremor, breathing difficulties and seizure/fits (see *Section 2 "Take special care"*)
- hallucinations, confusion, anxiety, sleep disturbances, nightmares, mood changes (mostly "highs", occasionally "lows") and changes in activity (usually appetite suppression), behaviour (e.g. in making decisions) and perception.
- dependence, abuse and addiction
- blurred vision
- worsening of asthma
- muscular weakness
- difficulty in passing or holding urine.

**Very rare** (affecting less than 1 in 10,000 users)

- an increase in liver enzymes
- withdrawal symptoms of panic attack, severe anxiety, hallucinations, numbness/tingling "pins and needles", ringing in the ears and other central nervous system symptoms.

**Other** (frequency not known: frequency cannot be estimated from the available data)

- worsening of asthma
- decrease in blood sugar level.

**"serotonin syndrome"** - signs of which are confusion, restlessness, fever, sweating, reduced coordination, increased sensitivity to stimuli, increased reflex actions, spasms/muscle contractions and diarrhoea. (See *Section 2 "Taking other medicines"* for further information).

This medicine may cause a physical dependence (addiction) with long term use. Withdrawal symptoms may occur, these include restlessness, nervousness, unable to sleep, hyperactivity, tremor and upset stomach.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRP Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: + 353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Tramapine 50 mg Capsules**

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store the product in its original package to protect from moisture. Do not use these capsules after the expiry date "EXP", which is the last day of that month stated on the blister strip and carton. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Contents of the pack and other information**

**What Tramapine 50 mg capsules contain:**

- the **active** substance is tramadol hydrochloride (50 mg per capsule).
- **other** ingredients: microcrystalline cellulose (E460), povidone K30, lactose monohydrate (see *end of Section 2 for further information*), magnesium stearate, sodium starch glycolate.
- **capsule shell:** titanium dioxide (E171), gelatin indigotine (E132), erythrosine (E127), yellow iron oxide (E172).
- **capsule ink:** shellac, propylene glycol, ammonia solution concentrated, potassium hydroxide, black iron oxide.

**What Tramapine 50 mg capsules look like and contents of the pack**

The hard gelatin capsules are green and yellow with "TRA 50" printed on both the cap and body. They are supplied in blister packs containing 30, 50, 100, 250 or 500 capsules and packed in cartons. Not all pack sizes may be marketed.

**Manufacturer**

Catalent Germany Schorndorf GmbH, Steinbeisstrasse 1 & 2, D-73614 Schorndorf, Germany.

**Marketing Authorisation Holder**

Pinewood Laboratories Ltd., Ballymacarby, Clonmel, Co. Tipperary, Ireland.

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