

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### TRAMADOL HYDROCHLORIDE CAPSULES 50MG (Tramadol Hydrochloride)

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- *Keep this leaflet. You may need to read it again.*
- *If you have further questions, please ask your doctor or your pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.*
- *If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (section 4).*

What is in this leaflet:

- 1. What Tramadol is and what it is used for**
- 2. What you need to know before you take Tramadol**
- 3. How to take Tramadol**
- 4. Possible side effects**
- 5. How to store Tramadol**
- 6. Contents of the pack and other information**

#### **1. WHAT TRAMADOL IS AND WHAT IT IS USED FOR**

Tramadol is the active substance in Tramadol Capsules. Your medicine belongs to a group of medicines called analgesics, which are more commonly known as painkillers. Such medicines act on the brain and spinal cord to reduce the amount of pain you experience. Tramadol is a painkiller belonging to the class of opioids that act on the central nervous system.

Tramadol capsules are used for the treatment and prevention of moderate to severe, a sudden or a long-standing pain (for example pain after an operation, or after an injury).

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRAMADOL**

##### **Do not take Tramadol if**

- you are allergic (hypersensitive) to Tramadol hydrochloride or to any of the other ingredients of this medicine (see section 6. Further Information).
- In acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions);
- you are taking, or you have taken in the last two weeks, monoamine oxidase inhibitors (MAOIs), these are medicines to treat depression (see 'Other medicines and Tramadol').
- you are suffering from uncontrolled epilepsy.
- as a substitute in drug withdrawal.

## **Warnings and precautions**

### **Talk to your doctor before taking Tramadol Capsules**

- If taken for long periods there is the rare possibility that addiction may develop.
- If you suffer from consciousness disorders (if you feel that you are going to faint);
- you are in a state of shock (cold sweat may be a sign of this);
- you suffer from increased pressure in the brain (possibly after a head injury or brain disease);
- you have recently had an accident where you may still be in shock (cold sweats may be a sign of this);
- you find it difficult to breathe, or your breathing is slower than normal.
- if you have a tendency towards epilepsy or fits because the risk of a fit may increase;
- If you have severe liver or kidney problems.

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 (400mg).

Please note that Tramadol may lead to physical and psychological addiction. When tramadol is taken for a long time, its effect may decrease, so that higher doses have to be taken (tolerance development).

In patients with a tendency to abuse medicines or who are dependent on medicines, treatment with tramadol should only be carried out for short periods and under strict medical supervision.

If any of the above apply to you, or if they applied to you in the past, please talk to your doctor or pharmacist for advice if you have not already done so.

## **Children and adolescents**

Tramadol Capsules are not suitable for children below the age of 12 years.

## **Other medicines and Tramadol**

Tell your doctor, pharmacist if you are taking, have recently taken or might take any other medicines.

- Monoamine – oxidase inhibitors (MAOIs); - if you are, or have taken in the last two weeks, an antidepressant medicine called a monoamine – oxidase inhibitors (MAOIs).
- The pain relief effect of tramadol may be weakened and/or shortened if you also take medicines containing:-
  - Carbamazepine (used to treat epilepsy)
  - Buprenorphine, nalbuphine, or pentazocine (pain killers)
  - Ondansetron (prevents nausea)
  - Medicines used to treat infections such as ketoconazole and erythromycin

Your doctor will tell you whether you should take Tramadol Capsules and what dose.

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

Tramadol capsules at the same time. Your doctor will tell you whether Tramadol capsules is suitable for you.

- if you are taking certain antidepressants. Tramadol 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 take tranquillizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking Tramadol capsules. You may feel drowsier or feel that you might faint. If this happens tell your doctor.
- if you take coumarin anticoagulants (medicines for blood thinning) e.g. warfarin, together with Tramadol capsules. The effect of these medicines on blood clotting may be affected and bleeding may occur.

#### **Tramadol Capsules with food and drink:**

Food does not influence the effect of Tramadol therefore it can be taken before, with or after food. You should **NOT** drink alcohol whilst taking this medicine as its effect may be intensified.

#### **Pregnancy, breast-feeding and fertility:**

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 Tramadol if you are pregnant. Chronic use during pregnancy may lead to withdrawal symptoms in newborns. Generally, the use of Tramadol is not recommended during breast-feeding. Small amounts of tramadol are excreted into breast milk. On a single dose it is usually not necessary to interrupt breast-feeding.

Based on human experience tramadol is suggested not to influence female or male fertility

Ask your doctor or pharmacist for advice before taking any medicine.

#### **Driving and using machines:**

Tramadol can cause drowsiness, dizziness and blurred vision particularly when combined with other medicines that can cause drowsiness or taken with alcohol or antihistamines and therefore may impair your reactions. Do not drive or operate heavy machinery unless you know how tramadol affects you.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine

**Important information about some of the ingredients of Tramadol**

Tramadol capsule contains lactose. If you have been told by your doctor that you have intolerance to some sugars, please contact your doctor before taking this medicine.

**3. HOW TO TAKE TRAMADOL**

Always take Tramadol capsules exactly as your doctor has told you. You should check with your doctor 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.

The usual doses for Tramadol are given below.

Adults and adolescents from the age of 12 years

The usual dose is 1 or 2 capsules (equivalent to 50mg – 100mg tramadol hydrochloride). Depending on the pain the effect lasts for about 4-8 hours.

Your doctor may prescribe a different, more appropriate dosage of Tramadol capsules if necessary.

The **maximum dose** is usually 400 mg daily

**Children:**

**(Under 12 years old):** Tramadol should not be taken by children under 12 years as it is not suitable for them.

**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.

**Severe liver or kidney disease (insufficiency)/dialysis patients**

Patients with severe liver and/or kidney insufficiency should not take Tramadol capsules. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

**How and when should you take Tramadol Capsules?**

Tramadol Capsules are for oral use.

Always swallow Tramadol Capsules whole, not divided or chewed, with sufficient liquid, preferably in the morning and evening. You may take the capsule on an empty

stomach or with meals.

**How long should you take Tramadol Capsules?**

You should not take Tramadol Capsules for longer than necessary. If you need to be treated for a longer period, your doctor will check at regular short intervals (if necessary with breaks in treatment) whether you should continue to take Tramadol Capsules and at what dose.

If you have the impression that the effect of Tramadol Capsules is too strong or too weak, talk to your doctor or pharmacist.

The capsules should be swallowed whole with a glass of water.

**If you take more Tramadol than you should:**

If you have taken an additional dose by mistake, this will generally have no negative effects. You should take your next dose as prescribed.

If you (or someone else) swallows several of these capsules all together, or you think a child has swallowed any of these capsules, contact your doctor or pharmacist or hospital emergency department immediately. Signs of an overdose include very small pupils, being sick, a fall in blood pressure, a fast heartbeat, collapse, unconsciousness, fits and breathing difficulties or shallow breathing. Always take any capsules left over with you, also the box and leaflet as this will allow easier identification of the capsules.

**If you forget to take Tramadol:**

If you forget to take a dose, pain is likely to return and you should take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose and just carry on as before. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Tramadol**

Do not stop taking Tramadol, or lower the dose, without first checking with your doctor. Your doctor may want you to gradually reduce the amount of Tramadol you are taking before stopping completely to ensure that you do not suffer from withdrawal symptoms.

If you interrupt or finish treatment with Tramadol Capsules too soon, pain is likely to return. If you wish to stop treatment on account of unpleasant effects, please tell your doctor.

Generally there will be no after-effects when treatment with Tramadol Capsules is stopped. However, on rare occasions, people who have been taking Tramadol Capsules for some time may feel unwell if they abruptly stop taking them.

**Withdrawal symptoms include:**

- agitation
- anxiety
- nervousness
- shaky
- confusion

- hyperactive
- problems sleeping
- gastrointestinal problems

Very few people may get:

- panic attacks
- delusions
- paranoia
- hallucinations
- feeling a loss of identity

Unusual perceptions:

- itching
- tingling
- numbness
- “ringing” in the ears (tinnitus)

If you experience any of these complaints after stopping Tramadol Capsules, please consult your doctor.

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

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Tramadol can have side effects, although not everybody gets them.

**Please stop taking this medicine and contact your doctor as soon as possible if you experience any of the following rare reactions:**

- allergic reaction such as difficulty in breathing, wheezing, swelling of the face or throat (occurs rarely), and/or or hives.
- anaphylactic reaction (an extreme allergic reaction) such as swollen face, tongue and/or throat and/or difficulty to swallow or hives together with difficulties in breathing (occurs rarely),.
- shock/sudden circulation failure

Usually the frequency of side effects is classified as follows:

**Very Common (may affect more than 1 in 10 people)**

- dizziness.
- nausea (feeling sick)

**Common ( may affect up to 1 in 10 people)**

- vomiting (being sick)
- headache.
- drowsiness (sleepiness)
- constipation, dry mouth
- sweating
- Fatigue including tiredness, weariness, weakness or low energy.

**Uncommon ( may affect up to 1 in 100 people)**

- Effects on the heart and blood circulation (pounding of the heart, rapid heartbeat, feeling faint or collapse), palpitation, flushing, sudden drops in blood pressure. These adverse effects may particularly occur in patients in an upright position or under physically strain
- urge to sick (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhoea skin reactions (e.g. itching, rash)

**Rare ( may affect up to 1 in 1,000 people)**

- slow heart beat
- increase in blood pressure
- abnormal sensations (e.g. itching, tingling, numbness), trembling, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), speech disorders.
- Epileptic fits have occurred mainly at high doses of tramadol or when tramadol was taken at the same time as other medicines which may induce fits.
- appetite changes.
- hallucination, confusional state, sleep disorders, delirium, anxiety and nightmares
- Psychic effects including: anxiety, changes in mood (mostly high spirits, occasionally irritated mood), activity (slowing down but sometimes an increase in activity), behaviour and perception, hallucinations, confusion, restlessness, sleep disturbances and nightmares.
- Drug dependence may occur. If Tramadol Capsules is taken over a long period of time dependence may occur, although the risk is very low. When treatment is stopped abruptly, signs of withdrawal may appear (see “If you stop taking Tramadol Capsules”).
- blurred vision , excessive dilation of the pupils (mydriasis), constriction of the pupil (miosis).
- slow breathing, shortness of breath (dyspnoea)
- worsening of asthma has been reported, however it has not been established whether it was caused by tramadol. If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down.
- weak muscles
- passing water difficult or painful, less urine than normal (dysuria)

**Very rare (may affect upto 1 in 10,000 people).**

- Increase in liver enzyme values

**Not known (frequency cannot be estimated from the available data)**

- decrease in blood sugar level

**Reporting of side effects**

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE TRAMADOL**

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date stated on the label or carton.
- Do not store above 25°C. Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. CONTENTS OF THE PACK AND OTHER INFORMATION**

**What Tramadol contains**

The **active** ingredient is: Tramadol Hydrochloride.

The **other** ingredients are: Lactose monohydrate, Microcrystalline cellulose (E460(i)), Croscarmellose sodium (E466) and Magnesium stearate (E572).

In addition to these ingredients Capsule shell contains:

Body: Erythrosine (E127), Titanium dioxide (E171), Yellow iron oxide (E172) and Gelatin.

Cap: Indigo carmine (E132), Titanium dioxide (E171), Black iron oxide (E172), Yellow iron oxide (E172) and Gelatin.

Printing Ink: Opacode S-1-17823 black contains Shellac glaze, Black iron oxide (E172), Propylene glycol (E1520) and Ammonium hydroxide (E527).

**What Tramadol looks like and contents of the pack**

Tramadol Capsules are olive and yellow colour capsules imprinted TRM on the capsule cap and 50 on the capsule body, and contain a white powder.

Tramadol Capsules are available in blister packs of 10, 30, 60 and 100 capsules (Not all pack sizes may be marketed).

**Marketing Authorisation Holder**

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