

PACKAGE LEAFLET: Information for the user

TRAMADOL

Capsules – 50 mg

(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 any further questions, ask your doctor or 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. See 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
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1. WHAT TRAMADOL IS AND WHAT IT IS USED FOR

Tramadol hydrochloride is the active substance in Tramadol 50 mg capsules. This 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 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 or to any of the excipients of this medicine (see section 6: Further Information);
- have recently taken excessive amounts of alcohol, sleeping medicines, other strong painkillers or medicines to treat mental illness;
- are taking, or you have taken within the last two weeks, monoamine oxidase inhibitor (MAOI) antidepressants (see section “Other medicines and Tramadol”);
- suffer from epilepsy (fits) not controlled by treatment from your doctor;
- are undergoing treatment to withdraw from use of narcotics.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tramadol capsules if you:

- have been or are actually addicted to alcohol, sleeping medicines, other strong painkillers, medicines to treat mental illness, or any other medicine;
- have epilepsy or suffered head injury or raised pressure in the skull (may cause painful eyes, changes in vision or headache behind the eyes);
- have liver, kidney or lung (breathing) problems;
- are in shock following a severe injury or blood loss;
- suffer from consciousness disorders (you feel that you are going to faint);
- suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see “Other medicines and Tramadol”);
- are sensitive to opiates.

There is a small risk that you may experience a so-called serotonin syndrome that can occur after having taken tramadol in combination with certain antidepressants or tramadol alone. Seek medical advice immediately if you have any of the symptoms related to this serious syndrome (see section 4 “Possible side effects”).

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).

Tolerance, dependence, and addiction

This medicine contains tramadol which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Tramadol can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Tramadol if:

- you or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”);
- you are a smoker;
- you have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Tramadol, it could be a sign that you have become dependent or addicted:

- you need to take the medicine for longer than advised by your doctor.
- you need to take more than the recommended dose;
- you are using the medicine for reasons other than prescribed, for instance, ‘to stay calm’ or ‘help you sleep’;
- you have made repeated, unsuccessful attempts to quit or control the use of the medicine;
- when you stop taking the medicine you feel unwell, and you feel better once taking the medicine again (‘withdrawal effects’).

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Tramadol).

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.

Sleep-related breathing disorders

Tramadol can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Tramadol:

- extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels). If you have these symptoms, contact your doctor, who will decide if you need to take hormone supplement.

Children and adolescents

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

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.

Other medicines and Tramadol

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

- Monoamine Oxidase Inhibitors (MAOIs, e.g. moclobemide), or have taken these within the last 2 weeks;
- any opioid medicines which include strong painkillers such as morphine, pethidine, buprenorphine, nalbuphine and pentazocine;
- medicines which slow your reactions and breathing down;
- carbamazepine (for epilepsy);
- sleeping medicines;
- ondansetron (to prevent feeling or being sick);
- warfarin (for thinning the blood);
- medicines that treat anxiety or mental illness;
- gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).

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 are suitable for you;
- if you are taking certain antidepressants, such as selective serotonin reuptake inhibitors, serotonin-noradrenaline reuptake inhibitors, MAO inhibitors, etc. Tramadol capsules may interact with these medicines and you may experience serotonin syndrome (see section 4 “Possible side effects”).

Concomitant use of Tramadol and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Tramadol together with sedative medicines, the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor’s dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Tramadol capsules with food, drink or alcohol

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 and breast-feeding

Pregnancy

If you are pregnant, 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.

Breastfeeding

Generally, the use of Tramadol is not recommended during breastfeeding. On a single dose it is usually not necessary to interrupt breast-feeding. Tramadol is excreted into breast milk. For this reason, you should not take Tramadol more than once during breastfeeding, or alternatively, if you take Tramadol more than once, you should stop breastfeeding.

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 if taken with alcohol or antihistamines and therefore may impair your reactions.

This 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.

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

3. HOW TO TAKE TRAMADOL

Always take Tramadol capsules exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Tramadol, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also section 2).

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 aged 12 years and over

Acute pain (such as after surgery): The recommended dose is 1 to 2 capsules 3 to 4 times a day. To be taken for as long as prescribed by your doctor.

Chronic pain (such as that associated with cancer): The recommended dose is 1 or 2 capsules at first, then 1 to 2 capsules every 4 to 6 hours according to the severity of your pain.

Take no more than 8 capsules (400 mg) in any 24 hour period unless told by your doctor.

- **Older people** above 75 years: the excretion of tramadol may be delayed. If this applies to you, your doctor may recommend prolonging the dosage interval.
- **Patients with liver or kidney impairment:** The recommended dose is one to two capsules every 12 hours. 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.
- **Use in children and adolescents:** Not recommended for use in children aged under 12 years.

How should you take Tramadol capsules?

Tramadol capsules are for oral use. Always swallow Tramadol capsules whole, not divided or chewed, with a glass of water.

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.

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) swallow more than one of these capsules at the same time, or you think a child may have swallowed any, 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

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

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.

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 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, shaking, confusion, hyperactivity, 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 cause 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:

- an allergic reaction: itching, skin rashes, swelling of the face, lips, tongue or throat, or wheezing, difficulty breathing or swallowing, narrowing of airways, worsening of existing asthma, shock or collapse;
- slowed breathing – usually when high doses of Tramadol capsules are being taken or with other medicines that slow breathing.

Tell your doctor if you notice any of the following side effects or notice any other unlisted effects:

Very common (may affect more than 1 in 10 users):

- dizziness
- nausea (feeling sick)

Common (may affect up to 1 in 10 users):

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

Uncommon (may affect up to 1 in 100 users):

- itchy rash
- itching
- fast heart beat
- palpitations and sudden heart problems
- dizziness on standing up due to low blood pressure
- diarrhoea
- retching
- bloating.

Rare (may affect up to 1 in 1,000 users):

- extreme sense of wellbeing (euphoria)
- false sense of uneasiness (dysphoria)
- confusion
- hallucinations (sensing things that are not real)
- altered mental state (delirium)
- changes in ability to think or sense clearly
- sleeping problems (including nightmares)
- anxiety
- ‘pins and needles’
- tremor

- muscle spasms
- fits
- fainting
- blurred vision
- slow heart beat
- high blood pressure
- changes in appetite
- muscle weakness
- difficulty urinating or inability to urinate.

Very rare (may affect up to 1 in 10,000 users):

- flushing.

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

- changes in liver enzyme levels (detected through blood tests), speech disorders, decrease in blood sugar level, hiccups, serotonin syndrome that can manifest as mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as fever, increase in heart rate, unstable blood pressure, involuntary twitching, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea) (see section 2 “What you need to know before you take Tramadol”).

You may become dependent on the capsules and find it difficult to stop taking them or feel you need to take them more often than necessary. If you stop taking the capsules suddenly you may suffer from withdrawal reactions (see section 3 for withdrawal symptoms).

5. HOW TO STORE TRAMADOL

Keep out from the reach and sight of children.

Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

Do not store above 25°C!

Do not use the medicinal product after the expiry date which is stated on the package.

6. FURTHER INFORMATION

What Tramadol capsules contain

The active substance is tramadol hydrochloride.

One Tramadol capsule contains 50 mg tramadol hydrochloride.

The excipients are: microcrystalline cellulose, pregelatinised starch, magnesium stearate, gelatin, yellow iron oxide, red iron oxide, titanium dioxide.

Content of the pack

Carton box of 20 capsules.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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