

Tramal® Capsules (Tramadol hydrochloride)

Read this entire leaflet carefully before you start taking this medicine.

- 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 personally and you should not pass it on to others. It may harm other people even if they have the same symptoms as you.
- If one of the side-effects causes you a lot of trouble or you notice side-effects that are not listed in this information leaflet, please inform your doctor or pharmacist.

This package information leaflet tells you:

1. What are Tramadol® capsules and what are they used for?
2. What must you take into account before using Tramadol® capsules?
3. How should you take Tramadol® capsules?
4. What side-effects may occur?
5. How should you store Tramadol® capsules?
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1. WHAT ARE TRAMAL® CAPSULES AND WHAT ARE THEY USED FOR?

Tramadol, the active substance in Tramadol® capsules is a painkiller belonging to the class of opioids that acts on the central nervous system. It relieves pain by acting on specific nerve cells of the spinal cord and brain. Tramadol® capsules are used for the treatment of moderate to severe pain.

2. WHAT MUST YOU TAKE INTO ACCOUNT BEFORE USING TRAMAL® CAPSULES?

Tramadol® capsules must not be taken:

- If you are allergic to tramadol or any of the other ingredients of Tramadol® capsules.
- In acute poisoning with alcohol, sleeping pills, painkillers or other psychotropic medicines (medicines that affect mood and emotions).
- If you are also taking MAO inhibitors (certain medicines used for depression) or have taken them in the last 14 days before treatment with Tramadol® capsules (see "Taking Tramadol® capsules with other medicines.")
- If you suffer or are an epileptic which cannot be adequately controlled by treatment.
- As a substitute in drug withdrawal.

Particular caution is necessary when taking Tramadol® capsules

- If you think that you are addicted to other painkillers (opioids).
- If you suffer from consciousness disorders (if you feel that you are going to faint).
- If you are in a state of shock (cold sweat may be a sign of it).
- If you suffer from increased pressure in the brain (possibly after a head injury or brain disease).
- If you have difficulty in breathing.
- If you have a tendency towards epilepsy or fits.
- If you suffer from a liver or kidney disease.

In such cases please consult your doctor before taking use.

Epileptic fits have been reported in patients using the recommended dose of tramadol. The risk may increase when the recommended maximum daily dose of 400 mg Tramadol. Please note that Tramadol® capsules may lead to physical and psychological addiction. When Tramadol® capsules are taken for a long time, their effect may decrease, and may have to take higher doses (tolerance development). In patients with a tendency towards medicine abuse or dependence, treatment with Tramadol® capsules should only be carried out for a short time and under strict medical supervision. Please also inform your doctor if one of these problems occurs during treatment with Tramadol® capsules or if they applied to you in the past.

Taking Tramadol® capsules with other medicines: Please inform your doctor or pharmacist if you are taking/using or have recently taken/used other medicines, even if they do not require a prescription. Tramadol® capsules should not be taken with MAO inhibitors (certain medicines for the treatment of depression). (See Tramadol capsules must not be used). The pain-relieving effect of Tramadol® capsules may be reduced and the length of time they act may be shortened, if you take medicines containing one of the following active substances:

- Carbamazepine (for epileptic fits).
- Pentazocine, nalbuphine or buprenorphine (painkillers).
- Ondansetron (for nausea).

Your doctor will tell you whether and if necessary in which dose you may take Tramadol® capsules.

The risk of side-effects increases:

- If you take medicines which also depress brain function together with Tramadol® capsules. You might feel dazed or that you are going to faint. If this happens, please inform your doctor. These other medicines include sedatives, sleeping pills and certain painkillers such as morphine and codeine (also as cough medicine) and alcohol.
- If you are also taking medicines that may cause fits, for example for the treatment of certain psychological diseases (like certain antidepressants). The risk of epileptic-like fits may rise, if you take Tramadol® capsules at the same time. Your doctor will tell you whether Tramadol® capsules are suitable for you.
- If you take selective serotonin re-uptake inhibitors (often called SSRI) or MAO inhibitors (special medicines used for the treatment of depression). The effects of these medicines and Tramadol® capsules might influence each other and this in isolated cases may lead to a "serotonin syndrome". Symptoms of serotonin syndrome are, for example, confusion, restlessness, high temperature, sweating, uncoordinated movements of the limbs or eyes, uncontrollable muscle twitching or diarrhea.
- If you take coumarin anticoagulants (medicines to prevent normal blood clotting), for example warfarin, at the same time with Tramadol® capsules. The action of these medicines on blood clotting may be affected and bleeding may occur.

Taking Tramadol® capsules together with food and drink: Do not drink alcohol during treatment with Tramadol® capsules, as their effect may be increased. Food has no effect on Tramadol® capsules.

Pregnancy and breast-feeding: Before using any medicines please ask your doctor or pharmacist for advice. There is very little information regarding safety of tramadol during pregnancy in humans. Therefore you should not take Tramadol® capsules if you are pregnant. The repeated use of Tramadol® capsules during pregnancy may lead to habituation in the unborn child and as a result, the child may experience withdrawal symptoms after birth.

In general if you are breast-feeding, you should not take tramadol. Very small amount of Tramadol are excreted into the breast milk. On a single dose of tramadol it is not usually necessary to stop breast-feeding. Please ask your doctor for advice.

Driving and Operating Machinery: Tramadol® capsules may lead to dizziness, muzziness and visual disorders and therefore affect your reaction: If you feel that your reactions are affected, do not drive a car or another vehicle, do not use electric tools or operate machinery, and do not work without a firm hold.

3. HOW SHOULD YOU TAKE TRAMAL® CAPSULES?

You should take Tramadol® capsules exactly according to your doctor's instructions. You should check with your doctor or pharmacist if you are not quite sure. The dosage should be adjusted to the intensity of your pain and your individual sensitivity. In principle, the lowest pain-relieving dose should be selected. Unless otherwise prescribed by your doctor, the usual dose is:

Adults and adolescents from the age of 12 years: For moderate pain one Tramadol® capsule (equivalent to 50 mg tramadol hydrochloride). If there is no effect after 30-60 minutes, a second capsule can be taken. If for severe pain a higher dose is necessary, two Tramadol® capsules (equivalent to 100 mg tramadol hydrochloride) can be taken. Depending on the intensity of the pain the effect lasts for 4-8 hours. Do not take more than eight Tramadol® capsules (equivalent to 400 mg tramadol hydrochloride) daily, unless told to do so by your doctor.

Children: Tramadol® capsules are not intended for use in children below the age of 12 years.

Elderly patients: In elderly patients (above 75 years) tramadol excretion may be delayed. If this applies to you, your doctor might recommend prolonging the intervals between doses.

Weak liver or kidney function (insufficiency)/dialysis patients: In patient with weak liver and/or kidney function the excretion of Tramadol is delayed. If this applies to you, your doctor might recommend prolonging the intervals between doses.

How and when should you take Tramadol® capsules? To be taken by mouth. Always swallow the capsules whole with sufficient amounts of liquid. You may take the capsules on an empty stomach or with meals.

How long should you take Tramadol® capsules? You should not take Tramadol® capsules for longer than absolutely necessary. If long-term pain treatment appears to be necessary, your doctor will check at regular short intervals (if appropriate with breaks in treatment) whether and to what extent you should continue taking Tramadol® capsules and if necessary, in which dose. Please consult your doctor if you feel that the effect of Tramadol® capsules is too strong or too weak.

If you have taken more Tramadol® capsules than you should: If you have taken an additional dose of Tramadol® capsules by mistake, this will generally have no negative effects. Take the next dose of Tramadol® capsules as prescribed. After taking very high amounts of the medicine, pin-point pupils, vomiting, fall in blood pressure, fast heart-beat, feeling faint, reduced level of consciousness up to coma (deep unconsciousness), epileptic-like fits, and difficulty in breathing up to stoppage of breathing may occur. In such cases call a doctor immediately!

If you have forgotten to take Tramadol® capsules: If you forget to take Tramadol® capsules, pain may return. Do not double the dose to make up for the dose you have forgotten, continue taking them as before.

If you stop treatment with Tramadol® capsules: If you interrupt or stop treatment with Tramadol® capsules too soon, pain is likely to return. If you wish to stop treatment on account of unpleasant side-effects, please consult your doctor. In general stopping treatment with Tramadol® capsules will have no after-effects. In a small number of patients taking Tramadol® capsules for a long time and suddenly stopping taking them, after-effects may occur. You might feel restless, anxious, nervous or dizzy.

You might be overactive, sleep badly, or have stomach or bowel trouble. A very small number of people might have panic attacks, hallucinations, abnormal sensations, such as tingling and numbness, or ringing in the ears (tinnitus). Future unusual central nervous system symptoms such as confusion, mania, changed perception of oneself (depersonalization) and reality (depersonalization), and paranoia have very rarely been observed. If one of these side effects occurs after stopping treatment with Tramadol® capsules, please consult your doctor. If you have any further questions regarding the use of this medicine, ask your doctor or pharmacist.

4. WHAT SIDE-EFFECTS MAY OCCUR? Like all medicines, Tramadol® capsules may have side-effects, which, however, do not occur in everyone. The incidence of undesirable effects is classified according to the following categories:

Very common: more than 1 in 10 people treated
Common: 1-10 in 100 people treated
Uncommon: 1-10 in 1,000 people treated
Rare: 1-10 in 10,000 people treated
Very rare: less than 1 in 10,000 people treated
Unknown: incidence cannot be estimated on the basis of the available data

The most common side effects during treatment with Tramadol® capsules are nausea and dizziness, which occur more frequently than 1 in 10 patients.

Psychiatric diseases:

Rare: hallucinations, confusion, anxiety, sleep disorders and nightmares. Psychological problems may appear after treatment with Tramadol® capsules. Their intensity and nature may vary (depending on the patient's personality and length of treatment). These may appear as a change in mood (mostly high spirits, occasionally irritated mood), changes in activity (usually suppression, occasionally increase) and decreased sensory and cognitive perception which may lead to errors in judgment (reduced ability to notice and recognize things). Dependence may occur.

Diseases of the nervous system:

Very common: dizziness.
Common: headache and muzziness.

Rare: changes in appetite, abnormal sensations on the skin (e.g. itching, tingling, numbness), trembling (tremor), slow breathing (respiratory depression), epileptic fits, muscle twitching, coordination disorders, temporary loss of consciousness (syncope). If you take more than the recommended doses or other drugs that depress brain function, your breathing may slow down. Epileptic-like fits occurred mainly after taking high doses of tramadol or when medicines that may lower the fit threshold were taken at the same time.
Not known: speech disorders.

Eye diseases:

Rare: blurred vision.
Not known: dilated pupils (mydriasis).

Heart diseases

Uncommon: effects on the heart and blood circulation (pounding of the heart, fast heart-beat (tachycardia), feeling faint (orthostatic hypotension), or collapse (cardiovascular collapse))
These side-effects may appear particularly when you are standing or sitting upright position or are under physical strain.

Rare: slow heart beat (bradycardia) and increases in blood pressure.

Diseases of the airways, chest and mediastinum:

Rare: breathlessness (dyspnoea).

Worsening of asthma has also been reported, but it has not been established whether it was caused by the active substance Tramadol.

Stomach and bowel diseases

Very common: nausea.
Common: vomiting, constipation and dry mouth.
Uncommon: urge to vomit, stomach trouble (e.g. feeling of pressure in the stomach, bloating) and diarrhea.

Liver and bile diseases:

Very rare: raised liver enzyme values.

Diseases of the skin and subcutaneous tissues

Common: sweating.
Uncommon: skin reactions (e.g. itching, red skin, rash).

Diseases of the muscles, connective tissues and bones

Rare: weak muscles (motorial weakness).

Diseases of the kidneys and urinary tract:

Rare: difficulty or pain on passing water and less urine than normal (micriturion disorders and dysuria).
General diseases and complaints at the site of administration:
Common: exhaustion.

Rare: allergic reactions (e.g. difficulty breathing (dyspnoea), wheezing, and accumulation of water in the tissues (angioneurotic oedema)) and shock reactions (sudden circulatory failure) have occurred in very rare cases. You should consult a doctor immediately, if you have symptoms such as swelling of the face, tongue and/or throat and/or difficulties in swallowing or skin rash with breathing difficulties at the same time. If Tramadol® capsules are taken over a long period of time dependence may occur, although the risk is very low. After stopping the medicine withdrawal reactions may occur. If one of the side-effects causes you a lot of trouble or you notice side-effects that are not listed in this patient information leaflet, please inform your doctor or pharmacist.

5. HOW SHOULD YOU STORE TRAMAL® CAPSULES?

Keep medicines out of children's reach. Do not use Tramadol® capsules after the expiry date printed on the package and the blister pack. The expiry date refers to the last day of the month.

Storage conditions: Do not store above 25°C. The medicine must not be thrown down the drain or into the rubbish bin. Ask your pharmacist how to dispose of the medicine when you no longer need it. This helps to protect the environment.

6. ADDITIONAL INFORMATION

What do Tramadol® capsules contain? The active substance is Tramadol hydrochloride. Each Tramadol® capsule contains 50 mg tramadol hydrochloride.

The other ingredients are:

Capsule Content: Microcrystalline cellulose, sodium carmellose Sodium (type A), colloidal anhydrous silica, magnesium Stearate.

Capsule Shell: gelatin, indigotene (E132), ferric oxides and hydroxides (E 172), titanium dioxide (E 171), sodium lauryl sulphate, capsugelink 1028 black.

What do Tramadol® capsules look like and what does the pack contain? Two-tone (green/bright yellow), glossy, oblong capsule.

Tramadol® capsules, 50 mg are available in packs of 10, 14, 30, and 50 capsules. Not all pack sizes are available in all markets.

Registration Number: 007/139/10, 14, 30, 50.

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This is medicament

- Medicament is a product, which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor
- Keep all medicaments out of reach of children.



