

Tramal[®] suppositories

Active substance: tramadol hydrochloride



Please read the following instructions for use 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 Tramal suppositories and what are they used for?
2. What must you take into account before using Tramal suppositories?
3. How should you use Tramal suppositories?
4. What side-effects may occur?
5. How should you store Tramal suppositories?
6. Additional information

1. WHAT ARE TRAMAL SUPPOSITORIES AND WHAT ARE THEY USED FOR?

Tramadol - the active substance in Tramal suppositories - 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. Tramal suppositories are used for the treatment of moderate to severe pain.

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

Tramal suppositories must not be used,

- if you are hypersensitive (allergic) to tramadol or any of the other ingredients of Tramal suppositories.
- 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 Tramal suppositories (see "Using Tramal suppositories with other medicines.")
- if you are an epileptic and your fits are not adequately controlled by treatment.
- as a substitute in drug withdrawal.

Particular caution is necessary when using Tramal suppositories,

- 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 use.

Epileptic fits have been reported in patients taking the recommended dose of tramadol. The risk may increase if you take more than the recommended maximum daily dose of 400 mg tramadol.

Please note that Tramal suppositories may lead to physical and psychological addiction. When Tramal suppositories are used for a long time, their effect may decrease, so that higher doses have to be taken (tolerance development). In patients with a tendency towards medicine abuse or dependence, treatment with Tramal suppositories 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 Tramal suppositories or if they applied to you in the past.

Using Tramal suppositories with other medicines

Please inform your doctor or pharmacist if you are using or have recently used other medicines, even if they do not require a prescription.

Tramal suppositories must not be used with MAO inhibitors (certain medicines for the treatment of depression) (see "Tramal suppositories must not be used"). The pain-relieving effect of Tramal suppositories 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 (prevents nausea).

Your doctor will tell you whether and if necessary in which dose you may take Tramal suppositories.

The risk of side-effects increases,

- if you take medicines which also depress brain function together with Tramal suppositories. 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 pain killers 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 Tramal suppositories at the same time. Your doctor will tell you whether Tramal suppositories 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 Tramal suppositories 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 diarrhoea;
- if you take coumarin anticoagulants (medicines to prevent normal blood clotting), for example warfarin, at the same time with Tramal suppositories. The action of these medicines on blood clotting may be affected and bleeding may occur.

Taking Tramal suppositories together with food and drinks

Do not drink alcohol during treatment with Tramal suppositories as their effect may be increased. Food has no effect on Tramal suppositories.

Pregnancy and breast-feeding

Before using any medicines please ask your doctor or pharmacist for advice.

There is very little information regarding the safety of tramadol during pregnancy. Therefore you should not take Tramal suppositories if you are pregnant.

The repeated use of Tramal suppositories 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 use tramadol. Very small amounts of tramadol are excreted into breast milk. On a single dose of tramadol it is not usually necessary to interrupt breast-feeding. Please ask your doctor for advice.

Driving and operating machinery

Tramal suppositories may lead to dizziness, muzziness and visual disorders (blurred vision) and therefore affect your reactions. 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 USE TRAMAL SUPPOSITORIES?

You should use Tramal suppositories 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

Adults and adolescents from the age of 12 years insert one Tramal suppository as a single dose (equivalent to 100 mg tramadol hydrochloride).

Depending on the intensity of the pain, the effect lasts for 4-8 hours. Do not take more than four Tramal suppositories (equivalent to 400 mg tramadol hydrochloride) daily, unless told to do so by your doctor.

Children

Tramal suppositories 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 patients 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 use Tramal suppositories?

To be inserted in the back passage.

Insert the suppositories into your back passage, if possible after bowel movement. For easy insertion you may warm the suppositories in your hand or dip them briefly into hot water.

How long should you use Tramal suppositories?

Do not use Tramal suppositories 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 using Tramal suppositories and if necessary, in which dose.

Please consult your doctor if you feel that the effect of Tramal suppositories is too strong or too weak.

If you have used more Tramal suppositories than you should

If you have used an additional dose of Tramal suppositories by mistake, this will generally have no negative effects. Take the next dose of Tramal suppositories as prescribed, but not before six hours have elapsed.

After using 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 use Tramal suppositories

If you forget to use Tramal suppositories, pain may return. Do not double the dose to make up for the dose you have forgotten, continue using it as before.

If you stop treatment with Tramal suppositories

If you interrupt or stop treatment with Tramal suppositories 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 Tramal suppositories will have no after-effects. In a small number of patients taking Tramal suppositories 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). Further unusual central nervous system symptoms such as confusion, mania, changed perception of oneself (depersonalisation) and reality (derealisation), and paranoia have very rarely been observed. If one of these side-effects occurs after stopping treatment with suppositories, 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, Tramal suppositories 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
Not known:	incidence cannot be estimated on the basis of the available data

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

Psychiatric diseases

Rare: hallucinations, confusion, sleep disorders, anxiety and nightmares.
Psychological problems may appear after treatment with Tramal suppositories. 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 judgement (reduced ability to notice and recognise things).
Dependence may occur.

Diseases of the nervous system

Very common: dizziness.
Common: headache, muzziness.
Rare: changes in appetite, abnormal sensations on the skin (e.g. itching, tingling, numbness), trembling (tremor), slow breathing (respiratory depression), epileptic fits, involuntary 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] and collapse [cardiovascular collapse]). These side-effects may appear particularly when you are standing or sitting upright or are under physical strain.
Rare: slow heart beat (bradycardia), increase 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.

Diseases of the stomach and bowels

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

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, less urine than normal (micturition disorders and dysuria).

General diseases and complaints at the site of administration

Common: exhaustion.
Rare: allergic reactions (e.g. difficulty in breathing [dyspnoea], wheezing, accumulation of water in the tissues [angioneurotic oedema]) and shock (sudden circulation 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 Tramal suppositories are taken over a long period of time dependence may occur, although the risk is very low. After you stop taking the medicine, withdrawal reactions may occur (see "If you stop treatment with Tramal suppositories").

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 SUPPOSITORIES?

Keep medicines out of the reach and sight of children.
Do not use Tramal suppositories after the expiry date printed on the package and the blister pack. The expiry date refers to the last day of the month.
Do not store above 30 °C.

Otherwise the suppositories will soften and may assume a different shape on cooling.

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 Tramal suppositories contain?

The active substance is: tramadol hydrochloride.

Each Tramal suppository contains 100 mg tramadol hydrochloride.

The other ingredients are:

Hard fat

What do Tramal suppositories look like and what does the pack contain?

White to yellowish wax-like suppositories

Tramal suppositories are available in packs of 10 and 20 suppositories.

Pharmaceutical company and manufacturer

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This patient information leaflet was last approved in September 2009

This is a 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 for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

SCHWARZ

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