
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

TRAMAL® (capsule): 50 mg tramadol hydrochloride.

Read all of this leaflet carefully before you start taking TRAMAL capsules.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- TRAMAL capsules have been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT TRAMAL CAPSULES CONTAIN

- The active ingredient is tramadol hydrochloride.
- The other ingredients in the capsule powder are: colloidal anhydrous silica, magnesium stearate microcrystalline cellulose, sodium starch glycolate.

The capsule shell is made of: gelatine, sodium lauryl sulphate, titanium dioxide (E171), and yellow iron oxide (E172).

2. WHAT TRAMAL CAPSULES ARE USED FOR

Tramadol, the active substance in TRAMAL capsules, is a painkiller belonging to the class of the opioids that acts on the central nervous system. It is used for the management of moderate to moderately severe pain.

3. BEFORE YOU TAKE TRAMAL CAPSULES

Do not take TRAMAL capsules:

- if you are allergic to tramadol or any of the other ingredients of TRAMAL capsules. (Refer to WHAT TRAMAL CONTAINS, above.);
- in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions);
- if you are taking MAO inhibitors (certain medicines used for depression) or have taken them in the last 14 days before treatment with TRAMAL capsules;
- If you have epilepsy;
- As a substitute in drug withdrawal;
- If you are pregnant or breastfeeding your baby (see Pregnancy and Breastfeeding).

Take special care with TRAMAL capsules:

- if you think that you are addicted to other pain relievers (opioids);
- if you suffer from consciousness disorders (if you have fainting spells or 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;

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- if you have a tendency towards epilepsy or seizures because the risk of a seizure may increase; especially if the upper dose limit (400 mg) of TRAMAL capsules is exceeded;
 - if you suffer from a liver or kidney disease.
 - Tramadol works by being converted (metabolised) into its active component. If you convert (metabolise) Tramadol to this active component more rapidly and completely than other patients you are known as an ultra-rapid metaboliser. If you are an ultra rapid metaboliser you are more likely to have serious side effects, such as breathing difficulties, with slow or shallow breathing. If you experience these types of side effects, stop taking this medicine and consult with your doctor immediately.
 - You may experience low levels of sodium in the blood (hyponatraemia) while taking this medicine. Symptoms of low blood sodium may include nausea and vomiting, headaches, feeling confused, feeling very tired, feeling restless, feeling irritable, muscle weakness, spasms or cramps and seizures. Elderly patients and patients taking other medicines that lower sodium in the blood are most at risk for this side effect. If you get any of these symptoms while taking TRAMAL, consult with your doctor immediately

TRAMAL capsules can lead to psychological and physical dependence or addiction in some people, especially with long term use. The dose needed to achieve the desired effect may increase with time. TRAMAL capsules should be used with caution, and only for short periods under strict medical supervision, in patients who are addicted to other opioid pain-killers.

Please also inform your doctor if any of these problems occur during TRAMAL capsules treatment or if they applied to you in the past.

Taking TRAMAL capsules with food and alcohol:

Do not drink alcohol during treatment with TRAMAL capsules as the effects of TRAMAL and alcohol may intensify each other. Food does not influence the effect of TRAMAL capsules.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking TRAMAL capsules.

If TRAMAL capsules are used on a long term basis during pregnancy, it will lead to harm (withdrawal symptoms) in newborns.

You should not take TRAMAL capsules if you are pregnant.

The use of TRAMAL capsules is not recommended during breastfeeding. TRAMAL is excreted into breast milk. If you are taking TRAMAL capsules you should not breastfeed your baby.

Driving and using machinery:

TRAMAL capsules may cause drowsiness, dizziness and blurred vision and therefore may impair your reactions. Do not drive a car or other vehicle, do not use electric tools or operate machinery until you are sure how TRAMAL capsules affects you.

Taking other medicines with TRAMAL capsules:

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).

TRAMAL capsules should not be used together with Monoamine oxidase (MAO) inhibitors (certain medicines for the treatment of depression), or within 2 weeks of stopping treatment with this.

The pain-relieving effect of TRAMAL capsules may be reduced and the length of time it acts may be shortened if you take medicines which contain:

- Carbamazepine (for epileptic seizures);
- Ondansetron (prevents nausea).

Your doctor will tell you whether you should have TRAMAL capsules, and at what dose.

The risk of side effects increases,

- If you are taking tranquilisers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while having TRAMAL capsules. You may feel drowsier or feel that you might faint. If this happens tell your nurse or doctor.
- If you are taking medicines which may cause seizures such as certain antidepressants or antipsychotics. The risk of having a seizure may increase if you take TRAMAL capsules at the same time. Your doctor will tell you whether TRAMAL capsules are suitable for you.

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- If you are taking certain antidepressants such as Selective Serotonin Reuptake Inhibitors or MAO inhibitors. TRAMAL capsules may interact with these medicines and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including 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 warfarin together with TRAMAL capsules. The effect of warfarin on blood clotting may be increased and bleeding may occur.

4. HOW TO TAKE TRAMAL capsules

Do not share medicines prescribed for you with any other person. Always take TRAMAL capsules exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The dosage should be adjusted to the intensity of your pain and your individual pain sensitivity. The lowest pain-relieving dose should be taken.

Do not take more than 400 mg TRAMAL capsules daily.

Capsules are to be taken whole, not divided or chewed, with sufficient liquid, with or without food.

Adults and children over 12 years:

Moderate pain: Take an initial dose of 50 mg tramadol (1 TRAMAL capsule), followed by 50 mg or 100 mg every 4 to 6 hours.

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Severe pain: Take an initial dose of 100 mg followed by 50 mg or 100 mg every 4 to 6 hours.

You should not take TRAMAL capsules for longer than is absolutely necessary.

Elderly patients (above 75 years):

A dose reduction and/or prolongation of the interval between doses are recommended.

Liver or kidney disease (insufficiency)/dialysis patients

If you suffer from liver and/or kidney insufficiency, the excretion of TRAMAL capsules may be delayed. Your doctor may direct you to prolong your dosage intervals.

How long should you take TRAMAL capsules?

You should not take TRAMAL capsules for longer than absolutely 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 TRAMAL capsules and at what dose.

If you take more TRAMAL than you should:

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

After taking very high doses, pin-point or wide pupils, vomiting, fall in blood pressure, fast heart beat, feeling faint, reduced level of consciousness up to coma (deep unconsciousness), epileptic seizures and difficulty in breathing up to stoppage of breathing may occur.

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In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take TRAMAL capsules

If you forget to take TRAMAL capsules, your pain may return. Do not take a double dose to make up for forgotten individual doses; simply continue taking TRAMAL capsules as before.

If you stop taking TRAMAL capsules

If you interrupt or finish treatment with TRAMAL capsules too soon, your pain may return. If you wish to stop treatment on account of unpleasant effects, please tell your doctor.

If you have been taking TRAMAL capsules for some time you may feel unwell if you abruptly stop treatment. You may feel agitated, anxious, nervous or shaky. You may be hyperactive, have difficulty in sleeping and have stomach or bowel disorders. You may get panic attacks, hallucinations, unusual perceptions such as itching, tingling and numbness, and noise in ears (tinnitus).

Further unusual Central Nervous System (CNS) symptoms, i.e. confusion, delusion, change in how you see (perceive) your own personality (depersonalisation), and change in how you see (perceive) reality (derealisation) and delusion of persecution (paranoia) have been reported. If you experience any of these effects after you stop taking TRAMAL CAPSULES, consult your doctor.

5. POSSIBLE SIDE EFFECTS

TRAMAL capsules can have side effects.

Not all side effects reported for TRAMAL capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TRAMAL capsules, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking TRAMAL capsules and tell your doctor immediately or go to your casualty department at your nearest hospital:

- swollen face, tongue and/or throat, and/or difficulty swallowing or breathing or wheezing;
- rash, swelling or itching of skin;
- shock (sudden circulation failure).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TRAMAL capsules. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice or experience any of the following:

- changes in the way your heart beats, for example, if you notice that your heart is beating faster;
- pounding (this may particularly occur when you are under strain, have a slow heartbeat, an increase in blood pressure or change position from an upright position to sitting or laying down);
- feeling faint;

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- loss of consciousness;
 - slow breathing;
 - shortness of breath;
 - seizures (fits);
 - passing urine with difficulty or pain, passing less urine than is normal for you.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- dizziness;
- headaches;
- drowsiness;
- abnormal sensations for example if you experience itching, tingling, or numbness;
- trembling;
- muscle twitches;
- uncoordinated movement;
- speech disorder;
- changes in appetite;
- hallucination;
- confusional state;
- sleep disorders;
- delirium;
- anxiety;
- nightmares;
- changes in mood for example you may feel happy or irritated;
- decreased activity;

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- restlessness;
 - changes in the way you see or view things;
 - blurred vision;
 - excessive widening of your pupils;
 - narrowing of the pupil;
 - nausea (feeling sick urge to vomit);
 - vomiting;
 - constipation;
 - dry mouth;
 - stomach trouble (e.g. feeling of pressure in the stomach, bloating);
 - diarrhoea (frequent or loose watery stools);
 - sweating more than is normal for you;
 - weak muscles;
 - liver enzyme increased;
 - fatigue.
 - Low levels of sodium in the blood and/or inappropriate antidiuretic hormone secretion (SIADH)

If any of the side effects get serious, or if you experience one of the above –mentioned serious side effects, call the nearest doctor immediately. If you experience any side effects not listed in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF TRAMAL capsules

Store TRAMAL capsules in a cool, dry place, at or below 30 °C. Store all medicines out of reach of children. TRAMAL capsules can be kept for only a limited period. Do not use TRAMAL capsules after the date (month and year) mentioned after “EXP”,

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even if it has been stored properly. Return unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF TRAMAL capsules

Blister packs of 10, 20, 100 or 500 capsules.

8. IDENTIFICATION OF TRAMAL capsules

Capsules: Oblong, hard gelatine capsule with snap-fit closure. Body and Cap: Yellow opaque.

9. REGISTRATION NUMBER

S/2.9/289

10. NAME AND ADDRESS OF REGISTRATION HOLDER



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11. DATE OF PUBLICATION

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