

TRAMOX CAPSULE

Tramadol hydrochloride 50mg

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What Tramox capsule is used for

Tramadol hydrochloride is the active substance in Tramox capsule. It is a painkiller belonging to the class of opioids that acts on the central nervous system (nervous system consisting of brain and spinal cord). Tramox capsule is used for the treatment of moderate to severe pain.

How Tramox capsule works

Tramox capsule relieves pain by acting on specific nerve cells of the spinal cord and brain.

Before you use Tramox capsule

- *When you must not use it*

Do not take Tramox capsule if you have any of the following medical conditions:

- if you are allergic (hypersensitive) to Tramadol hydrochloride or any of the other ingredients of Tramox capsule
- in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions);

- if you are also taking Monoamine oxidase inhibitors (MAOIs) (certain medicines used for treatment of depression) or have taken them in the last 14 days before treatment with Tramox capsule (see “*Taking other medicines*”);

- *Before you start to use it*

Tell your doctor or pharmacist:

- if you think that you are addicted to other pain relievers (opioids);
- if you suffer from consciousness disorders (if you feel that you are going to faint);
- if you are in a state of shock;
- 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 because the risk of a fit may increase;
- if you suffer from a liver or kidney disease;

Do not take Tramox capsule if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Tramox capsule if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- *Taking other medicines*

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines when taken with Tramox capsule may interfere with each other.

These include:

- MAOIs
- centrally acting drugs including alcohol
- selective serotonin reuptake inhibitors (SSRIs), tricyclic anti-depressants, for the treatment of depression
- Lithium, medicine for depression
- triptans, medicine for migraine
- coumarin anticoagulants (medicines for blood thinning)
- Carbamazepine, medicine for fit
- Cimetidine, medicine for gastric
- Quinidine, medicine for infection and also for heart

Taking Tramox capsule with food and drink

Do not drink alcohol during treatment with Tramox capsule as its effect may be intensified. Food does not influence the effect of Tramox capsule.

How to use Tramox capsule

- *How much to use*

Always take Tramox capsule exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will prescribe the most suitable dose for you based on the intensity of your pain.

The usual dose is:

Adults and adolescents from the age of 12 years

One or two Tramox capsule (equivalent to 50 mg – 100 mg)

Your doctor may prescribe a different, more appropriate dosage of Tramox capsule if necessary. Do not take more than 8 Tramox capsule (equivalent to 400 mg Tramadol hydrochloride) daily, except if your doctor has instructed you to do so.

Children

Tramox capsule is not suitable for children below the age of 12 years.

Elderly

In elderly (above 75 years) your doctor may recommend prolonging the dosage interval.

Severe liver or kidney disease

If you have severe liver or kidney disease, you should not take Tramox Capsule. Your doctor may recommend prolonging the dosing interval if your condition is mild or moderate liver or kidney impairment.

- When to use it

Always swallow Tramox capsule whole, not divided or chewed, with sufficient liquid.

- How long to use it

You should not take Tramox capsule 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 Tramox capsule and at what dose. If you have the impression that the effect of Tramox capsule is too strong or too weak, talk to your doctor or pharmacist.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is

almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Taking too many tablets may cause constricted of the pupils, vomiting, cardiovascular collapse, sedation, coma, epileptic fits, and difficulty in breathing up to cessation of breathing may occur.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Tramox capsule.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor. If you interrupt or finish treatment with Tramox capsule 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 Tramox capsule is stopped. However, on rare occasions, people who have been taking Tramox capsule

for some time may feel unwell if they abruptly stop taking them.

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

Do not take any new medicines without consulting your doctor.

Do not give Tramox capsule to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Tramox capsule may cause drowsiness and therefore may impair your reactions. If you feel that your reactions are affected, do not drive a car or other vehicle, do not use electric tools or operate machinery.

Side effects

Like all medicines, Tramox capsule can cause side effects, although not everybody gets them.

In case one of the following situations occur, see your doctor straight away:

- nausea, dizziness
- dry mouth, headache, sweating
- stomach and intestinal irritation (a feeling of pressure in the stomach)
- vomiting
- constipation
- effects on the circulation e.g. palpitation (feel your heartbeat), tachycardia (rapid heartbeat), faintness or circulatory collapse
- skin reactions including itching (pruritus) and rash.
- changes in appetite
- changes in mood: usually high spirits (elation), occasionally an unpleasant mood (dysphoria)

- changes in activity (usually less active, occasionally more active)
- changes in your ability to think and feel things clearly such as: making decisions and perception disorders
- weak muscles
- urination problem
- allergic reaction
- extending to shock
- respiratory depression
- sedation
- fit
- giddiness

If Tramox capsule 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 "*Things you must not do*"). If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Tramox capsule

- *Storage*

Keep out of the reach and sight of children.
Do not use Tramox capsule after the expiry date which is stated on the carton and the blister.

The expiry date refers to the last day of that month.
Do not store above 25°C, protected from light and humidity.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your

pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

Tramox capsule 50mg are buff, hard gelatin capsule, containing white to off-white granular powder packed in blisters of 10x10 capsules.

- *Ingredients*

Active ingredient

The active substance in Tramox capsule 50mg is Tramadol Hydrochloride. Each capsule contains 50 mg of Tramadol Hydrochloride.

Inactive ingredients

Magnesium stearate, Calcium hydrogen phosphate anhydrous, Colloidal silicon dioxide.

- *MAL number*

MAL08042453ACZ

Manufacturer

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Product Registration Holder

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