

TRAMADA CAPSULE

Tramadol Hydrochloride (50mg)

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What TRAMADA is used for

TRAMADA is used for the treatment of moderate to severe pain.

How TRAMADA works

TRAMADA 50mg capsule contains the active ingredient tramadol hydrochloride. Tramadol belongs to a class of drugs known as opioid pain-relief medicines that acts on the central nervous system. It relieves pain by acting in the brain and spinal cord, and subsequently blocks the feeling of pain.

Before you use TRAMADA

- When you must not use it

Do not take this medicine:

- if you are allergic to tramadol hydrochloride or any ingredients of this medicine (listed in Product Description).
- if you are under 12 years old.
- if you are under the influence of alcohol, sleeping pills, pain relievers (e.g. opioids) or other psychotropic medicines (medicines that affect mood and emotions).
- if you are taking antidepressant medicines (monoamine oxidase inhibitors) or have taken them in the last 14 days before treatment with TRAMADA.
- for narcotic withdrawal treatment.
- if you have slow or shallow breathing, or other breathing problems.
- to treat pain after surgery to remove the tonsils and/or adenoids in children under 18 years old.
- if you are between the age of 12 and 18

years old who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.

Pregnancy and lactation

Do not take TRAMADA during pregnancy. Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or think you might be pregnant before using TRAMADA.

Do not take TRAMADA during breastfeeding. Small amounts of tramadol is secreted into the breastmilk. It is advisable to stop breastfeeding during the treatment with tramadol. However, if only a single dose is taken, it is usually not necessary to interrupt breastfeeding. If you have taken TRAMADA when you are breastfeeding, seek immediate medical attention if you notice your baby has any changes in their breathing (such as weak, difficult or fast breathing).

- Before you start to use it

Tell your doctor or pharmacist if you:

- suffer from consciousness disorders (if you feel that you are going to faint).
- suffer from increased pressure in the brain.
- have a tendency of developing seizures or fits.
- have severe kidney or liver disease.

As with all medicines of this type, TRAMADA capsule may lead to psychological and physical dependence or addiction in some people. When TRAMADA is taken for a long time, the dose needed to achieve the desired effect may increase with time (tolerance development). Therefore, in individuals with a tendency to abuse medicines or who are dependent on medicines, treatment with tramadol should only be carried out for short periods and under strict medical supervision.

- Taking other medicines

Tell your doctor or pharmacist if you are taking:

- Monoamine Oxidase Inhibitors (MAOIs), or have taken these within the last 2 weeks.

- any opioid medicines which include strong pain killers such as morphine etc.
- medicines which slow down your reactions and breathing.
- carbamazepine (medication for epilepsy/seizure).
- sleeping medicines.
- medicines to treat depression or other mental illnesses including tricyclic antidepressant; e.g. selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs).
- central nervous system depressant such as tranquilizers or sedative hypnotics.

Taking TRAMADA with a benzodiazepine (medicine used as sedatives or to treat anxiety) can cause effects such as very deep sleep, slow breathing, and unconsciousness. Remember to tell your doctor or pharmacist if you are currently taking benzodiazepine.

If you are taking any other medicines, including those you buy without a prescription from a pharmacy, supermarket or health food store, please tell your doctor or pharmacist.

How to use TRAMADA

- How much to use

Always follow the instructions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label please ask your doctor or pharmacist for help.

- The dosage of TRAMADA will be given according to the intensity of pain.
- Always swallow TRAMADA capsule whole, with sufficient liquid, not divided or chewed.
- You may take the capsule on an empty stomach or with meals.

- Single dose:

Adults and adolescents (12 years and older and weigh more than 25kg):

Take 1-2 capsules (50-100mg TRAMADA capsule) as a single dose. If pain relief is not satisfactory, you may

take another capsule after about 30 to 60 minutes.

For severe pain, higher dose (2 capsules) can be given initially.

The pain relief may last between 4-8 hours depending on the severity of pain. Do not take more than 8 capsules (400mg) per day.

Your doctor will adjust the dose according to your condition if you are an elderly or individual with kidney/liver impairment.

- When to use it

Take TRAMADA every 4 to 6 hours or as directed by your doctor or pharmacist. If you are having kidney/liver impairment, take TRAMADA every 12 hours.

- How long to use it

Use TRAMADA for the duration the doctor recommends. Do not use TRAMADA for longer than prescribed as dependence on this medication may occur.

Please consult your doctor if you feel that your condition has not improved or getting worse after taking TRAMADA.

- 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 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 capsules may cause very small pupils, vomiting, heart and blood circulation may stop working, become unconscious to the point of falling into a deep coma, seizures, and might have trouble breathing, which could even lead to not breathing at all.

While you are using it

- Things you must do

- Use this medication only for the condition prescribed and only with a doctor's prescription.
- Tell all the doctors, dentists and pharmacists treating you that you are taking TRAMADA before taking any other new medication.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop using the medicine unless advised by your doctor.
- Do not use any new medicine without consulting your doctor or pharmacist.
- Do not give TRAMADA to anyone else, even if they have the same symptoms or condition as you.
- Do not take this medicine together with alcohol.

- Things to be careful of

- Seek medical attention at once if you experience any allergic reaction or difficulty in breathing.

Driving and using machines

TRAMADA may make you feel drowsy or dizzy. This may be made worse if you drink alcohol or take other medicines such as strong painkillers with TRAMADA. Make sure you are not affected before you drive or operate machinery.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any serious side effects after taking this medicine.

Common side effects are:

- nausea, vomiting, dizziness, sweating, dry mouth and fatigue.
- effects on the heart and blood circulation, palpitation or fast heartbeat, feeling faint or collapse when standing up.

- headache, constipation, stomach irritation, digestive problems and skin reaction.

Rare:

Slow and shallow breathing (respiratory depression).

Very rare cases:

Physical weakness, appetite changes, urination problems, and various mental and emotional effects like mood swings, changes in activity levels, and alterations in thinking and sensory (see, hear, taste, smell, pain response) abilities.

Isolated cases:

Seizure, allergic reaction and shock.

Post Marketing Experience:

Reduced interest in sex, difficulty getting or maintaining an erection, missed periods in women, and also infertility.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of TRAMADA

- Storage

- Keep out of the reach and sight of children.
- Store in a cool, dry place below 30°C, protect from direct sunlight and moisture.
- Do not use this product after the expiry date.

- Disposal

- Medicines should not be disposed of via wastewater or household waste.
- Ask your pharmacist on how to dispose of medicines that are no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

White powder filled in opaque pink capsule imprinted with black figure C.B.LAB on body and cap.

- Packing

It is available in blister pack, with 10 capsules in a strip. Each paper box contains 10 strips (100 capsules).

- Ingredients

Active ingredient:

Each capsule contains 50mg of Tramadol hydrochloride.

Inactive ingredients:

Talc, Magnesium Stearate, Lactose, Sodium Lauryl Sulphate.

- MAL number

MAL20031921AZ

Manufacturer

Charoen Bhaesaj Lab Co., Ltd.
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Product Registration Holder

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