

TRAMADOLOR® 50 CAPSULES

Tramadol HCl (50 mg)

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What Tramadol® is used for

Tramadol® contains the active ingredient Tramadol hydrochloride. It is used to treat moderate to severe pain.

How Tramadol® works

Tramadol® is classified as a pain reliever medicine. It works by blocking a chemical messenger from reaching the brain to interpret pain. The chemical messenger called prostaglandin is secreted by injured or damaged cell.

Before you use Tramadol®

- When you must not use it

Do not take **Tramadol**® if you:

- Have allergic reaction to the active ingredient Tramadol hydrochloride or to any other ingredients in this product.
- Recently take large amount of alcohol.
- Taking any other pain killers.
- Taking any medicines that may affect your alertness or mood including medicines for psychiatry problems.
- Taking monoamine oxidase (MAO) inhibitors or within two weeks of their withdrawal
- In acute poisoning with alcohol, hypnotics, centrally analgesics, opioids, or psychotropic medicinal products
- Are less than 12 years old
- Have slow or shallow breathing, or other breathing problems.
- Are pregnant
- Are breastfeeding.

If you are not sure whether you should start taking this medicine, consult your doctor.

- Before you start to use it

Tell your doctor if you:

- Have thyroid hormone deficiency.

- Have adrenal insufficiency (adrenal gland not producing enough of its hormone)
- Have history of head injury or increase pressure inside the skull.
- Have history with seizure.
- Have respiratory problem.
- Have opioids dependency.
- Have abdominal problems.
- Have liver and kidney problems.
- To treat pain after surgery to remove the tonsils and/or adenoids in children younger than 18 years old.
- Are adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnoea or severe lung disease.

- Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription. You may need to use different amounts of these medicines, or you may need to take different medicines. Your doctor will advise you. In particular, tell your doctor if you take any of the following:

- Carbamazepine (anticonvulsant) to treat seizures and nerve pain.
- Monoamine oxidase inhibitor (MAOI) to treat depression, migraine and Parkinson's disease.
- Digoxin to treat congestive heart failure.
- Warfarin to prevent blood clots formation.
- Quinidine to treat irregular heartbeat.
- Cimetidine to treat ulcer and heartburn.
- Alcohol
- Anaesthetic agent used in surgery.
- Medicines for depression or other mental problems including tricyclic antidepressant; e.g., amitriptyline and Selective Serotonin Reuptake Inhibitors e.g., fluoxetine.
- Central nervous system depressant such as opioids, tranquilizers or sedative hypnotics.
- CYP3A4 inhibitor such as ketoconazole (antifungal) or erythromycin (antibiotics)

Taking **Tramadol**® with a benzodiazepine (medicine used as sedatives or to treat anxiety) can depress your central nervous system. Inform your doctor if you are currently taking any benzodiazepine.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

- Pregnancy and lactation

Tell your doctor if you are pregnant; think you are pregnant or planning to become pregnant. **Tramadol**® is not recommended during pregnancy.

Tell your doctor if you are breastfeeding or about to start breastfeeding. **Tramadol**® is not recommended for mothers who are breastfeeding. Your doctor may choose another treatment for you if you wish to breastfeed.

How to use Tramadol®

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

- *Adults and adolescents of 14 years and above*

Take 1-2 capsules as a single dose. If there is not adequate pain relieved within 30-60 minutes, a single second dose of 1 capsule of **Tramadol**® may be given. The pain relief may last about 4-8 hours depending on individual. Do not exceed 8 capsules per day.

- *Geriatric patient with normal renal and hepatic function (65 years old and above)*
Take 1-2 capsules every 4-6 hours as needed.

- *Geriatric patient (75 years old and above)*
Dosage not exceeding 300mg daily.

- *Adults and children with creatinine less than 30 ml/min (16 years old and above)*
Take 1-2 capsules every 12 hours, not exceeding 4 capsules daily.

- *Adults and children with hepatic cirrhosis (16 years old and above)*
Take 1 capsule every 12 hours.

- When to use it

Take your medicine as directed by your doctor or pharmacist.

- How long to use it

Continue to take your medicines as long as your doctor tells you. The duration of treatment depends on the medical condition being treated which could range from few days to few months. Your doctor will be able to advise you on this.

- 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 reduced consciousness, seizure, low blood pressure, rapid heartbeat, constricted/dilated pupils and difficulty breathing.

While you are using it

- Things you must do

- Always take **Tramadol**[®] exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.
- Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription such as supplements or traditional medicines.
- Inform your doctor or pharmacist immediately if you notice any side effects, or if the side effects get serious or anything else that make you feel unwell.
- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking **Tramadol**[®].
- If you are going to undergo surgery. Tell the surgeon or anesthetist that you are taking **Tramadol**[®], as tramadol may affect other medicines used during surgery.

- Things you must not do

- Do not use **Tramadol**[®] after the expiry date which is stated on the carton and blister.
- Do not give this medication to anyone else, even if they have the same condition as you.
- Do not stop taking your medicines without consulting your doctor.

- Things to be careful of

- Serotonin syndrome: **Tramadol**[®] may cause a rare but potentially life-threatening condition resulting from concomitant

administration of serotonergic drugs. If you have some or all these symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.

- Adrenal insufficiency: Long-term use of **Tramadol**[®] may cause adrenal insufficiency, a potentially life-threatening condition that may present with non-specific symptoms and signs such as nausea, vomiting, decreased appetite, fatigue, weakness, dizziness and low blood pressure. Seek medical attention if you experience a constellation of these symptoms.
- Infertility: Long-term use of **Tramadol**[®] may cause reduced fertility. It is not known whether these effects on fertility are reversible.
- Tramadol is not to be used during breast-feeding. Small amounts of tramadol is excreted into breast milk. On a single dose it is usually not necessary to interrupt breast-feeding. If you have taken **Tramadol**[®] 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).
- Driving and using machines: Be careful when driving or operating machineries while you are taking **Tramadol**[®]. **Tramadol**[®] may cause drowsiness, blurred vision and dizziness.

Be careful when drinking alcohol while taking this medicine. Alcohol may worsen the dizziness or drowsiness effects.

Side effects

All medicines can have side effects. **Tramadol**[®] may cause unwanted side effects although not everybody gets them.

Tell your doctor or pharmacist if you notice the following side effects:

Immune system disorder

- Allergic reaction
- Anaphylaxis

Metabolism and nutrition disorder

- Changes in appetite
- Low blood glucose

Psychiatric disorders

- Hallucinations
- Confusion
- Sleep disturbance
- Nervousness
- Nightmares

- Changes in mood
- Changes in activity
- Changes in cognitive and sensorial capacity
- Dependence may occur

Nervous system disorders

- Dizziness
- Headache
- Drowsiness
- Speech disorders
- Tingling sensation
- Tremor
- Convulsion
- Involuntary muscle contractions
- Abnormal coordination
- Temporary loss of consciousness

Eye disorders

- Blurred vision
- Dilation of the pupil
- Excessive constriction of the pupil

Cardiac disorders

- Palpitation
- Abnormal heart rate
- Increase in blood pressure

Vascular disorders

- Low blood pressure that happens when you stand up from sitting or lying down
- Cardiovascular collapse

Respiratory, thoracic and mediastinal disorders

- Shortness of breath
- Respiratory depression

Gastrointestinal disorders

- Nausea
- Vomiting
- Constipation
- Dry mouth
- Retching
- Gastrointestinal discomfort
- Diarrhoea

Hepatobiliary disorders

- Increase in liver enzyme value

Skin and subcutaneous tissue disorders

- Excessive sweating
- Itching
- Rash
- Swelling

Musculoskeletal and connective tissue disorders

- Muscle weakness

Renal and urinary disorders

- Difficult urination
- Urinary retention

General disorders and administration site conditions

- Fatigue

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

Storage and Disposal of Tramadol[®]

Storage

Store in a cool, dry place below 30°C. Protect from light.

Keep out of the reach and sight of children.

- 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

Tramadol[®] 50 Capsule is a snap-fit, green cap and yellow body, hard gelatin capsule, containing a white odorless powder.

- Ingredients

- Active ingredient

Each capsule contains 50mg of Tramadol hydrochloride.

- Inactive ingredients

Magnesium stearate, sodium starch glycollate, calcium hydrogen phosphate dihydrate.

- Packing

It comes in strip of 10 capsules and packed in box of 1, 3, 5 and 10 blisters.

- MAL Number

MAL19985903ACZ

For

Hexal AG
Industriesße 25,
83607 Holzkirchen, Germany.

Product Registration Holder

IMEKS Pharma Sdn. Bhd.
No. 5 & 9, Jalan Udang Harimau 2,
Medan Niaga Kepong,
51200 Kuala Lumpur, Malaysia.

Serial Number

NPRA(R2/1)220221/837

Date of revision

1/3/2022

Manufacturer

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39179 Barleben, Germany.