

TRACIDOL[®] CAPSULE 50MG

Tramadol Hydrochloride 50mg

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What TRACIDOL CAPSULE is used for

TRACIDOL CAPSULE is used for the management of moderate to severe pain.

How TRACIDOL CAPSULE works

TRACIDOL CAPSULE relieves pain by acting on specific nerve cells of the spinal cord and brain.

Before you use TRACIDOL CAPSULE

- When you must not use it

Do not use TRACIDOL CAPSULE:

- if you are less than 12 years old
- if you have slow or shallow breathing, or other breathing problems
- if you are pregnant
- if you are breastfeeding
- Tracidol must not be used for children younger than 18 years to treat pain after surgery to remove tonsils and/or adenoids.
- Tracidol must not be used for adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.

- if you are known hypersensitivity towards tramadol or any of the excipients.
- if you are in acute poisoning with alcohol, sleeping pills, pain relievers, opioids 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.
- Tracidol must not be used for narcotic withdrawal treatment.

- 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 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.
- if you are experiencing minor pain.

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

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

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines when taken with TRACIDOL CAPSULE may interfere with each other. These include:

- MAO inhibitors, medicines used for depression
- centrally depressant substances including alcohol, carbamazepine, medicine for fit mixed agonist/antagonists (e.g. buprenorphine, nalbuphine, pentazocine), narcotic analgesics.
- selective serotonin re-uptake inhibitors, tricyclic antidepressants, and neuroleptic, for psychiatric disorder.
- ketoconazole and erythromycin, medicines used to treat infection.
- benzodiazepines, medicines used to treat panic attacks, insomnia, seizures, restless leg syndrome, and alcohol withdrawal.

Taking TRACIDOL CAPSULE with 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 usual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking medication.

How to use TRACIDOL CAPSULE

- How much to use

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.

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

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Adults and adolescents > 12 years old:

50 – 100mg (1 – 2 capsules) every six hours as needed.

An initial dose of 50mg is usually more effective for moderate pain whereas an initial dose of 100mg is usually more effective for more severe pain.

Tramadol is not approved for use in patients below 12 years old.

Maximum daily dose:

400mg, except in special clinical circumstances.

Elderly:

In elderly (above 75 years) your doctor may recommend prolonging the dosage interval/ downward adjustment of the dose.

Hepatic and renal insufficiency / dialysis:

In acute pain, a dosage adjustment is not necessary as Tramadol is given only once or a few times. In patients with severe renal and/or hepatic insufficiency, Tramadol should not be administered. In less severe cases, prolongation of the dosage interval is recommended.

Paediatric:

The safety and efficacy of tramadol has not been studied in the paediatric population. Therefore, use of tramadol is not recommended in patients under 12 years of age.

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Please refer to doctor or pharmacist.

If TRACIDOL CAPSULE is taken over a long period of time dependence may occur, although the risk is very low.

Please do not take TRACIDOL CAPSULE longer than doctor recommends.

- *If you forget to use it*

If you miss a dose of TRACIDOL CAPSULE take it as soon as possible. If it is approaching time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

- *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 capsule may cause constricted of the pupils, vomiting, cardiovascular collapse, reduce level of consciousness, coma, epileptic fits, and difficulty in breathing up to cessation of breathing may occur.

While you are using TRACIDOL CAPSULE

- *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 TRACIDOL CAPSULE.

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

- *Things you must not do*

Tramadol may affect or impair the ability to drive or operate machinery, particularly when used in conjunction with other psychotropic medicines or alcohol.

- *Things to be careful of*

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 TRACIDOL CAPSULE when are

breast-feeding, seek immediate medical attention if you notice your baby has any changes in their breathing (such as weak, difficult or fast breathing).

Serotonin syndrome: TRACIDOL CAPSULE may cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. If you have some or all of these symptoms: feeling confused, feeling restlessness, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.

Adrenal insufficiency: Long-term use of TRACIDOL CAPSULE 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 TRACIDOL CAPSULE may cause reduced fertility. It is not known whether these effects on fertility are reversible.

Side effects

Possible side effects include nausea, dizziness, vomiting, constipation, sweating, dry mouth, headache and muzziness (mentally confusion). Some other side effects that rarely happens such as palpitation and tachycardia (abnormal in heartbeat), postural hypotension or cardiovascular collapse (unstable conditions happens when have low blood pressure), gastrointestinal irritation, dermal reactions such pruritus and urticaria (itching of skin), rashes, motorial weakness, changes in appetite, blurred vision, micturition disorders (difficult in passing urine and urinary retention),

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various psychic side effects including changes in mood and activity as well as changes in cognitive and sensorial capacity, allergic reactions such as dyspnoea, bronchospasm, wheezing (breathing discomfort), angioneurotic oedema (swelling of the dermis), and anaphylaxis, worsening of asthma, epileptiform convulsions (involuntary contractions of voluntary muscle), increase in blood pressure and bradycardia (slow heart reaction), respiratory depression.

Dependence may develop. Symptoms of withdrawal reactions, similar to those occurring during opiate withdrawal may occur.

Risk of side effects will be higher for individuals with CYP2D6 ultra-rapid metabolizer.

Profound sedation, respiratory depression, coma and death may result from concomitant use of Tramadol with benzodiazepines.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

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 TRACIDOL CAPSULE

- Storage
Store below 30°C, protect from light & moisture.
- Disposal
If your doctor or pharmacist tells you to stop using TRACIDOL CAPSULE or the batch has passed the expiry date, ask your doctor or pharmacist what to do with any that is left over.

Product description

- What it looks like
A yellow body, green cap hard gelatin capsule containing white powder.
- Ingredients
 - Active ingredient:
Tramadol Hydrochloride
 - Inactive ingredient:
Cellulose
Magnesium Stearate
Sodium Starch Glycolate
Silicon Dioxide
- MAL number
MAL06111398AZ

Manufacturer and Product Registration Holder

Y.S.P. Industries (M) Sdn. Bhd.
Lot 3, 5, 7, 12 & 14, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru
Bangi, 43000 Kajang, Selangor,
Malaysia.

Date of revision

27/02/2026

Serial Number

NPRA(R2/1)190321/88