

TRACIDOL® PROLONGED RELEASE CAPSULE

Tramadol Hydrochloride (100mg)

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What *Tracidol*® is used for

Tracidol® is indicated for treatment of moderate to severe pain.

How *Tracidol*® works

Tramadol is a centrally acting analgesic. Tramadol is a non – selective, pure agonist in the μ , and K opiate receptors, and it attaches itself most effectively to the μ -receptor. Other factors that contribute to its analgesic effects are inhibition of neuronal re-uptake of noradrenaline and enhancement of 5-HT release.

Tramadol has an antitussive effect. In opposition to morphine, analgesic doses of tramadol do not produce respiratory depression during a wide interval. Tramadol does not affect to gastrointestinal motility and its effects on the cardiovascular system are mild.

Antinociceptive efficacy of Tramadol has been shown with osteoarthritis patients.

Before you use *Tracidol*®

- When you must not use it

Patients with severe renal or hepatic insufficiency, have slow or shallow breathing, or other breathing problems, children under 12 years, hypersensitivity to Tramadol or to or to any of the excipients, acute intoxication with alcohol, hypnotics drugs, centrally acting analgesics, opioids or psychotropic drugs.

Also contraindicated in patients who are receiving monoamine oxidase (MAO) inhibitors or within two weeks of their withdrawal, epilepsy not controlled by treatment, and breast-feeding (if long term treatment is necessary) are not recommended.

Pregnancy and lactation

Do not take *Tracidol*® if you are pregnant, trying to get pregnant or think you may be pregnant.

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

- Before you start to use it

Please refer to doctor or pharmacist.

- Taking other medicines

Tell your doctor if you are taking any other medicines (non-selective MAO inhibitors, selective-A MAO inhibitors, selective B-MAO inhibitors, alcohol, Benzodiazepines, Carbamazepine and other enzyme inducers, and Opioid agonists-antagonists (buprenorphine, nalbuphine, pentazocine)), including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Taking *Tracidol*® 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.

How to use *Tracidol*®

- How much to use

Adults and children over 12 years: Usual starting dosage is one capsule of 100-200 mg per day. If this dosage

does not relieve the pain, raise the dosage until pain is relieved.

Elderly people: Patients under 75 years of age with normal liver and kidney functions can be given the normal dosage for adults. In patients over 75 years of age the half-life of Tramadol is prolonged. For those patients, an adjustment of the dosage may be required. If the dosage is increased the condition of the patient must be closely monitored.

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.

- When to use it

Should be administered every 24 hours, dosage varies by individual patient; use as directed by your doctor or pharmacist.

- How long to use it

Continue taking *Tracidol*® for as long as your doctor recommends.

- 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.

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Taking too many tablets may cause miosis, emesis, cardiovascular collapse, sedation and coma, seizures and respiratory depression can occur.

While you are using it

- Things you must do

Epileptic patients controlled by a treatment or patients susceptible to seizures should be treated with tramadol only if there are compelling circumstances.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Tracidol*®.

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

- Things you must not do

In severe respiratory insufficiency, moderate and severe renal insufficiency, moderate hepatic insufficiency, and concomitant use of opioid agonist-antagonists, Tramadol is not recommended.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Tracidol*® to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines. Alcohol and other medicinal products, which depress the central nervous system, may increase this effect.

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* 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).

Serotonin syndrome: *Tracidol*® 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 restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.

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

Side effects

Like all medicines, *Tracidol*® can cause side effects, although not everybody gets them.

The most commonly reported undesirable effects caused by the medicinal product are nausea and dizziness.

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

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of *Tracidol*®

- Storage

Keep out of the reach and sight of children.

Store below 30°C, protect from light and moisture.

- 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

Hard gelatin capsules with a light blue cap and white opaque body containing white pellets.

- Ingredients

Tracidol 100mg Prolonged Release Capsule

- Active ingredient(s)
Tramadol hydrochloride

- Inactive ingredients
Cellulose
Sucrose Monostearate
Magnesium Stearate
Polysorbate 80
Polyacrylate Dispersion
Simethicone
Hypromellose
Talc

- MAL number(s):
MAL06121025ACZ

TRACIDOL[®] PROLONGED RELEASE CAPSULE

Tramadol Hydrochloride (100mg)

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Product Registration Holder

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