

TRADOL TABLET

Tramadol Hydrochloride / Paracetamol (37.5mg/325mg)

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1. What TRADOL is used for
TRADOL is used to treat moderate to severe pain when your doctor recommends that a combination of tramadol hydrochloride and paracetamol is needed.

2. How TRADOL works
TRADOL tablets have a combination of two pain relievers - tramadol hydrochloride (an opioid analgesic) and acetaminophen. You may already be familiar with acetaminophen, which acts quickly to relieve pain. Tramadol hydrochloride is a pain reliever that works over several hours to maintain pain relief. Because these two ingredients work together, TRADOL tablets relieve your pain quickly and help that pain relief last longer.

3. Before you use TRADOL

When you must not take it•

•if you are hypersensitive or have had an allergic reaction (for instance skin rash, swelling of the face, wheezing or difficulty breathing) to tramadol, paracetamol or any of the other

ingredients in TRADOL

- in cases of acute alcohol poisoning
- if you are taking sleeping pills, pain relievers or medicines that affect mood and emotions
- if you are also taking medicines called monoamine oxidase inhibitors (MAOIs) or have taken MAOIs in the last 14 days before treatment with TRADOL.
- MAOIs are used in the treatment of depression or Parkinson's disease.
- if you have a severe liver disorder
- If you have epilepsy that is not adequately controlled by your current medicine.
- 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.

Before you start to take it

Before you take TRADOL, check with your doctor or pharmacist if you

- take other medicines containing paracetamol or tramadol
- have liver problems or disease as your eyes and skin may turn yellow, which may suggest jaundice
- have kidney problems
- have severe difficulties in breathing, for example asthma or severe lung problems

- have epilepsy or have already experienced fits or seizures
- have recently suffered from a head injury, shock or severe headaches associated with vomiting (being sick)
- are dependent on any medicine (for example morphine)
- take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine
- are going to undergo a procedure that requires anesthesia (tell your doctor or dentist that you are taking TRADOL).

ALLERGY

ALERT:

Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters and rash. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Taking other medicines

There are other medications that may cause TRADOL tablets to be less effective, or may cause you to have some side effects or drug reactions.

Drugs that may interact with TRADOL include:

ketoconazole, erythromycin, lithium or St. John's Wort, triptans, linezolid fluoxetine, paroxetine, quinidine, amitriptyline, carbamazepine, MAO inhibitors and serotonin reuptake inhibitors, digoxin, warfarin-like compounds.

This preparation contains PARACETAMOL. Do not take any other paracetamol containing medicines at the same time.

You must tell your doctor and pharmacist if you are taking any

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other medications.

Taking Tradol tablet 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.

4. How to take TRADOL

How much to take it

Take TRADOL as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Swallow the tablets whole with sufficient liquid.

Do not break or chew the tablets.

Take TRADOL for as short a time as possible and no longer than your doctor has told you.

Adults and adolescents over 16 years:

The recommended dosage is to start with 1 to 2 tablets every 4 to 6 hours or according to doctors advice. If required, further doses may be taken, as instructed by your doctor.

The shortest time between doses must be at least 4 hours.

Do not take more than 8 tablets per day.

Your doctor may increase the time between doses if:

- you are older than 75 years
- you have kidney problems
- you have liver problems.

Children under 16 years of age:

- not recommended.

When to take it

You may take TRADOL tablets with or without food.

How long to take it

Take TRADOL for as short a time as possible and no longer than your doctor has told you.

If you forget to take it

If you forget to take the tablets, pain is likely to return.

Do not take a double dose to make up for forgotten individual doses; simply continue taking the tablets as before.

If you take too much (overdose)

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

5. While you are using TRADOL

Things you must do

If you think that the effect of TRADOL is too strong (you feel very drowsy or have difficulty breathing) or too weak (you do not have enough pain relief), contact your doctor.

Things you must not do

Do not take any other paracetamol containing medicines at the same time.

Do not take TRADOL while you are breastfeeding, as small amounts of tramadol may pass into the breast-milk.

Things to be careful of

- TRADOL may be habit-forming and should be used only by the person it was prescribed for. Never share this medication with

another person, especially someone with a history of drug abuse or addiction. Keep the medication in a place where others cannot get to it.

- Tramadol is not to be used during breast-feeding. A small amount of tramadol is excreted into breast milk. On a single dose it is usually not necessary to interrupt breast-feeding. If you have taken Tradol tablet 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: Tradol tablet 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 Tradol tablet 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,

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dizziness, and low blood pressure. Seek medical attention if you experience a constellation of these symptoms. Infertility: Long-term use of Tradol tablet may cause reduced fertility. It is not known whether these effects on fertility are reversible.

6. Side effects

Like all medicines, TRADOL can cause side effects, however not everybody gets them.

Some side effects could be serious. Contact your doctor immediately if any of the following occur:

- rarely cases of skin rash, indicating an allergic reaction, may develop with sudden swelling of the face and neck, difficulties breathing or drop of blood pressure and fainting. If this happens to you, stop treatment. Do not take the medicine again.
- Additionally, if any of the following side effects get serious, contact your doctor or pharmacist:**
- nausea
- dizziness, drowsiness.
- vomiting (being sick), digestion problems (constipation, flatulence, diarrhoea), stomach pain, dry mouth
- itching, sweating
- headache, shaking
- confusion, sleep disorders, mood changes (anxiety, nervousness, feeling of high spirits).

This is not a complete list of side effects. For any unexpected effects while taking TRADOL contact 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 visiting the website npra.gov.my [Consumers ☐ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. After using TRADOL

Storage

Store below 30°C

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.

8. Product description

What it looks like

A beige color oval shaped film coated tablet

Ingredients

Microcrystalline cellulose, Sodium Starch Glycolate, Pregelatinized Starch, Magnesium Stearate, Corn Starch, Hydroxypropylmethycellulose, Polyethylene Glycol, Propylene Glycol, Talc, Titanium dioxide, Yellow Iron Oxide

MAL NO: MAL12115053AZ

9. Product registration

Holder & Manufacturer

Noripharma Sdn. Bhd. (792633-A)
Lot 5030, Jalan Teratai,
51/2 Mile Off Jalan Meru
41050 Klang,
Selangor Darul Ehsan
Malaysia

10. Date of revision

March 2022

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