

UNIDOL CAPSULE

Tramadol Hydrochloride 50 mg Capsules

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What is UNIDOL CAPSULE used for

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

How UNIDOL CAPSULE works

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

Before you use UNIDOL CAPSULE

-When you must not use it

Do not use Unidol:

- 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 with Unidol.
- Unidol must not be used for narcotic withdrawal treatment.
- You are less than 12 years old
- You have slow or shallow breathing, or other breathing problem
- You are pregnant
- You are breastfeeding

Pregnancy and lactation

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

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

-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.

-Taking other medications

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 Unidol may interfere with each other.

These include:

- MAO inhibitors, medicines used for depression
- centrally depressant substances including alcohol
- carbamazepine, medicine for fit
- Lithium
- selective serotonin re-uptake inhibitors, tricyclic antidepressants, and neuroleptic, for psychiatric disorder
- CYP2D6 inhibitors

Taking Unidol 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.

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

How to use UNIDOL 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.

Unidol is not approved for use in individuals below 12 years old.

Dosage should be adjusted according to intensity of the pain.

For adults and adolescents over 12 years of age, swallow 1 to 2 capsules with at least half glass of water every 4 to 6 hours, as needed for pain. Do not crush or chew the capsule. Not to exceed 8 capsules (400mg) of UNIDOL CAPSULE in a day.

Dose adjustment is needed in patients with liver and kidney impairment.

Please consult your doctor or pharmacist before consuming UNIDOL capsule.

-When to use it

The capsules are to be taken whole, not divided or chewed, with sufficient liquid, independent of meals.

-How long to use it

Continue taking Unidol for as long as your doctor recommends.

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-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 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 it

-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 Unidol.

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

-Things you must not do

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

Do not take any new medicines without consulting your doctor.

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

-Things to be careful of

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

-Adrenal insufficiency: Long-term use of UNIDOL 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 UNIDOL CAPSULE 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 Unidol 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

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 and contact your doctor immediately.

Side effects

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

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

Side effects include nausea, vomiting, constipation, dizziness,

vertigo, dry mouth, sweating, headache, motor weakness, abnormal in heartbeat, palpitations, low blood pressure when stand up from sitting position, hypothermia (reduce body temperature), restlessness, mood and libido changes, micturition difficulties (difficult in passing urine and urinary intention), increased intracranial pressure (brain), and respiratory depression (rare).

Postmarketing experience:

- Serotonin syndrome e.g. agitation, hallucinations, coma, automatic instability, incoordination, nausea, vomiting, diarrhea and can be fatal
- Adrenal insufficiency e.g. extreme fatigue, weight loss, decreased appetite, darkening of skin, low blood pressure, nausea, diarrhea, vomiting and salt craving
- Androgen deficiency (Body has lower levels of male sex hormones, symptoms e.g. reduced sexual desire, hot flushes and sweating, breast development, lethargy and fatigue, depression, reduced muscle mass and strength)
- 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 UNIDOL CAPSULE

-Storage

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.

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Product Description

-What it looks like

Hard gelatin capsule shells of size '4' with yellow opaque cap and yellow opaque body marked as 'T50' with black ink on cap containing a white to off white powder.

-Ingredients

Active ingredient(s)

Tramadol Hydrochloride

Inactive ingredient(s)

Microcrystalline Cellulose, (PH 101), Sodium Starch Glycolate, Colloidal, Anhydrous Silica, Magnesium Stearate, Purified water, Hard Capsule Shell

-MAL number

MALXXXXXXXXX

Manufacturer

MEDREICH LIMITED

Unit – 7, Survey No. 11, 12, 13, 14 and 15, Poojaramanahalli Village, Bangalore Rural District, IN-562114, INDIA.

Product Registration Holder

Healol Pharmaceuticals Sdn. Bhd.,
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