

# ANADOL CAPSULE

Tramadol hydrochloride (50mg)

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## What Anadol is used for

Anadol is used for the management of moderate to severe pain.

## How Anadol works

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

## Before you use Anadol

### - When you must not use it

Do not use Anadol:

- 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 Anadol.
- Anadol 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 Anadol if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Anadol if you are breastfeeding. 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 a tendency towards epilepsy.
- if you are experiencing minor pain.

### - 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 Anadol 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 Anadol 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 Anadol

### - 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.

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

### *Adults and adolescents (> 12 years old):*

**Acute Pain:** An initial dose of 100mg is usually necessary and can be followed by doses of 50 or 100mg not more frequently than 4 hourly.

**Pain Associated with Chronic Conditions:** Use an initial dose of 50mg and then titrate dose according to pain severity.

### *Maximum daily dose:*

400 mg, except in special clinical circumstances.

### *Geriatric patients:*

The usual dosages may be used.

The dosing will be adjusted accordingly for liver and kidney impaired individuals.

### - 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 Anadol 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.

Taking too many capsules 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 Anadol.

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 Anadol to anyone else, even if they have the same symptoms or condition as you.

- *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 Anadol 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, Anadol 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](http://npra.gov.my) [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

**Storage and Disposal of Anadol**

- *Storage*

Keep out of the reach and sight of children.

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.

**Product Description**

- *What it looks like*

Hard gelatin capsule filled with white granular powder having a green color cap and white color body imprinted 'Square' on both parts.

- *Ingredients*

- Active ingredient

Tramadol Hydrochloride

- Inactive ingredients

Magnesium stearate

Colloidal anhydrous silica

Dibasic calcium phosphate, anhydrous

Sodium starch glycolate

Microcrystalline cellulose

- *MAL number(s):*

MAL11060026AZ

**Manufacturer**

SQUARE PHARMACEUTICALS LTD.

Dhaka Unit, Kaliakoir, Gazipur

Bangladesh

**Product Registration Holder**

Medispec (M) Sdn Bhd

No. 55 & 57, Lorong Sempadan 2

11400 Ayer Itam, Penang, Malaysia

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