

# Tramadol Hydrochloride 50mg capsules

## Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

## Index

### 1 What Tramadol capsules are and what they are used for

### 2 Before you take

### 3 How to take

### 4 Possible side effects

### 5 How to store

### 6 Further information

### 1 What Tramadol capsules are and what they are used for

Tramadol hydrochloride is one of a group of medicines called centrally acting analgesics and are used for the relief of moderate or severe pain.

### 2 Before you take

**Do not take Tramadol capsules and tell your doctor if you:**

- are **allergic** (hypersensitive) to tramadol hydrochloride, or any of the ingredients (see section 6).
- are **pregnant, planning to become pregnant or breast-feeding**.
- have recently taken **alcohol, sleeping tablets, other strong pain killers or medicines to treat mental illness**.
- have taken a monoamine oxidase inhibitor (**MAOI**) antidepressant within the last two weeks.
- have **severe liver, kidney or lung** (breathing) problems.
- suffer from **epilepsy (fits) not controlled by treatment** from your doctor.
- are **undergoing treatment to withdraw** from use of narcotics.

## Check with your doctor or pharmacist

before taking Tramadol capsules if you:

- have been or are presently **addicted to alcohol or any other drug**.
- have **epilepsy** or suffered **head injury** or **raised pressure** in the skull (may cause painful eyes, changes in vision or headache behind the eyes)
- have **liver, kidney or lung** (breathing) problems which are not severe.
- are in **shock** following a severe injury or blood loss.

## Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- Monoamine Oxidase Inhibitors (MAOIs, e.g. moclobemide), or have taken these within the last 2 weeks.
- any opioid medicines which include strong pain killers such as morphine, pethidine, buprenorphine, nalbuphine and pentazocine.
- medicines which slow your reactions and breathing down.
- carbamazepine (for epilepsy or nerve pain).
- sleeping tablets.
- strong pain killers such as morphine, pethidine, buprenorphine, nalbuphine and pentazocine.
- warfarin (for thinning the blood).
- medicines to treat depression (including fluoxetine, paroxetine, amitriptyline or lofepramine).
- medicines to treat anxiety or mental illness.

## Pregnancy and Breast-feeding

Do not take Tramadol capsules if you are pregnant, think you may be pregnant or are breast-feeding. Ask your doctor or pharmacist for advice before taking this medicine.

## Driving and using machines

Tramadol capsules may make you feel drowsy or in rare cases blur your vision. This may be made worse if you drink alcohol or take other medicines such as strong painkillers with tramadol. Make sure you are not affected before you drive or operate machinery.

### 3 How to take

Always take Tramadol capsules exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

You are advised **NOT to drink alcohol** with this medicine. The effects of Tramadol capsules are not affected by food.

Swallow these capsules **whole with a glass of water** at the same times each day.

#### Doses:

- **Adults and children aged 12 years and over**

**Acute pain** (such as after an operation): One to two capsules three to four times a day. To be taken for as long as prescribed by your doctor.

**Chronic pain** (such as that associated with cancer): one or two capsules at first, then one to two capsules every 4 to 6 hours according to the severity of your pain.

- **Take no more than eight capsules (400mg) in any 24 hour period unless told to by your doctor.**

- **Elderly:** One to two capsules every 9 hours.
- **Patients with liver or kidney impairment:** One to two capsules every 12 hours.
- **Children:** Not recommended for use in children aged under 12 years

#### If you take more than you should

If you (or someone else) swallow a lot of capsules at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include narrowed pupils, being sick, heart problems, sleepiness, coma, fits and breathing difficulties.

#### If you forget to take the capsules

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

#### If you stop taking the capsules

**Do not stop** treatment early because you may experience withdrawal effects. If you stop taking the capsules you may develop agitation, anxiety, nervousness, panic attacks, difficulty sleeping, tremor, over-activity, pins and needles or ringing in the ears. **Talk to your doctor** before you stop taking the capsules and follow their advice.

### 4 Possible side effects

Like all medicines, Tramadol capsules can cause side effects, although not everybody gets them. Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.

**Contact your doctor at once** if you experience:

- an **allergic reaction:** itching, skin rashes, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing, narrowing of airways, worsening of existing asthma, shock or collapse.
- **slowed breathing** - usually when high doses of Tramadol capsules are being taken or with other medicines that slow breathing.

**Tell your doctor** if you notice any of the following side effects or notice any other effects not listed:

- **Very common** (more than 1 in 10 users): dizziness, feeling or being sick.

- **Common** (less than 1 in 10 users): increased sweating, 'pins and needles', tremor, tiredness, drowsiness, sleepiness, headache, stomach ache, dry mouth, constipation.
- **Uncommon** (less than 1 in 100 users): itchy rash, itching, fainting, fast heart beat, palpitations and sudden heart problems, dizziness on standing up due to low blood pressure, retching and bloating.
- **Rare** (less than 1 in 1000 users): extreme sense of wellbeing (euphoria), false sense of uneasiness (dysphoria), confusion, hallucinations (sensing things that are not real), altered mental state (delirium), changes in ability to think or sense clearly, sleeping problems (including nightmares), fits, blurred vision, slow heart beat, high blood pressure, changes in appetite, muscle weakness, difficulty urinating or inability to urinate.
- **Very rare** (less than 1 in 10,000 users): flushing.
- **Not known** (cannot be estimated from the available data): changes in liver enzyme levels (detected through blood tests).

You may become dependent on the tablets and find it difficult to stop taking them or feel you need to take them more often than necessary. If you stop taking the tablets suddenly you may suffer from withdrawal reactions (see section 3 for withdrawal symptoms).

### 5 How to store

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not use Tramadol capsules after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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.

### 6 Further information

#### What Tramadol capsules contain

- The active substance (the ingredient that makes the tablet work) is tramadol hydrochloride.
- The other ingredients are pregelatinised starch, microcrystalline cellulose (E460), magnesium stearate
- The capsule shell contains gelatin, iron oxide (E172), titanium dioxide (E171), indigo carmine (E132). The printing ink contains shellac glaze and iron oxide black (E172).

#### What Tramadol capsules look like and contents of the pack

Tramadol capsules are yellow and green, opaque, hard gelatin capsules.

Pack sizes are 30 and 100.

#### Marketing Authorisation Holder

Actavis, Barnstaple, EX32 8NS, UK

#### Manufacturers

Actavis, Barnstaple, EX32 8NS, UK

or  
Balkanpharma-Dupnitsa AD,  
3 Samkovsko Shosse Str.,  
Dupnitsa 2600, Bulgaria

Date of revision: January 2010



Actavis, Barnstaple, EX32 8NS, UK