Tramadol hydrochloride 50mg capsules

What is this leaflet

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 What you need to know before you take Tramadol capsules

Do not take Tramadol capsules if you:
- are allergic to tramadol hydrochloride, or any of the ingredients of this medicine
- are pregnant, planning to become pregnant or breast-feeding
- have recently taken a monoamine oxidase inhibitor (MAOI), or have taken these within the last 2 weeks.
- have a severe liver, kidney or lung (breathing) problem
- have epilepsy (fits) not controlled by treatment from your doctor
- are undergoing treatment to withdraw from use of narcotics.

Warnings and precautions:

Talk to 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)

Other medicines and Tramadol capsules

The risk of side effects increases:
- if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics.
- if you are taking certain antidepressants. Tramadol capsules may interact with these medicines and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38 °C.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine. 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.
- simetidine (for gastric ulcers).
- ketoconazole or erythromycin (for infections).
- cimetidine (for gastric ulcers).
- carbamazepine (for epilepsy or nerve pain).

Other important warnings:

- taking a painkiller for headaches too often or for too long can make them worse.

Pregnancy and Breast-feeding

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

Driving and using machines

Tramadol capsules may make you feel drowsy, dizzy 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.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.
- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.

Other important warnings:

- taking a painkiller for headaches too often or for too long can make them worse.
- taking a painkiller for headaches too often or for too long can make them worse.
4. Possible side effects

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

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 sick.
- Common (less than 1 in 10 users): increased sweating, tiredness, drowsiness, sleepiness, headache, stomach ache, dry mouth, being sick, constipation.
- Uncommon (less than 1 in 100 users): itchy rash, itching, fast heart beat, palpitations and sudden heart problems, dizziness on standing up due to low blood pressure, diaphoresis, 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), anxiety, ‘pins and needles’, tremor, muscle spasms, fits, fainting, 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), speech disorders, decrease in blood sugar level.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tramadol capsules

Keep out of the sight and reach 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.

Do not throw away this medicine of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Tramadol capsules contain

- The active substance 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 (E110).

The printing ink contains shellac glaze, iron oxide black (E172) and propylene glycol.

What Tramadol capsules look like and contents of the pack

Tramadol capsules are yellow and green, opaque, hard gelatin capsules. Pack sizes are 50 and 100.

Marketing Authorisation Holder and Manufacturer

Actavis, Barnstaple, EX32 8NS, UK

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