Tramadol hydrochloride
50mg capsules

Other important warnings:
• taking a painkiller for headaches too often or for too long can make them worse.

Other medicines and Tramadol capsules
Concomitant use of Tramadol capsules and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Tramadol capsules together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedative medicines you are taking, and follow your doctor’s dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

The risk of side effects increases:
• if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk of having a fit may increase if you take Tramadol capsules at the same time. Your doctor will tell you whether Tramadol capsules is suitable for you.
• 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 30 °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, butorphanol, nalbuphine and pentazocine.
• medicines which slow your reactions and breathing down (carbamazepine (for epilepsy or nerve pain), sleeping tablets, cimetidine (for gastric ulcers), ketorolac or etoricoxib (for infections), condorisor (to prevent feeling or being sick), warfarin (for thinning the blood), medicines to treat depression (including fluoxetine, paroxetine, amitriptyline or trazodone), medicines to treat anxiety or mental illness.

Children and adolescents
Use in children with breathing problems
Tramadol is not recommended in children with breathing problems, since the symptoms of tramadol toxicity may be worse in these children.

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.

Pregnancy and breast-feeding
Do not take Tramadol capsules if you are pregnant. If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Breast-feeding
Tramadol is excreted into breast milk. For this reason, you should not take Tramadol capsules more than once during breast-feeding, or alternatively, if you take Tramadol capsules more than once during breast-feeding, your breast milk will contain more of the medicine and may affect your baby. Breast-feeding should be stopped if you need to take this medicine.

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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 advisable to drive if this medicine affects your ability to drive.
• However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

1 How to take Tramadol capsules
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Swallow these capsules whole with a glass of water at the same times each day.
Doses:
The dosage should be adjusted to the intensity of your pain and your individual pain sensitivity. In general the lowest pain relieving dose should be taken.
• Adults and children aged 12 years and over
Acute pain (such as after an operation): The recommended dose is 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): The recommended doses 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.
• Older people: above 75 years: the excretion of tramadol may be delayed.
In this case the recommended dose gradually to reduce the chance of developing unnecessary side effects.
• Patients with liver or kidney impairment: The recommended dose is one to two capsules every 12 hours. Patients with severe liver and/or kidney insufficiency should not take Tramadol capsules.
If your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.
• Use in children and adolescents: Not recommended for use in children aged under 12 years.
How long should you take Tramadol Capsules
You should not take Tramadol Capsules for longer than necessary. If you need to be treated for a longer period, your doctor will check at regular short intervals (if necessary with breaks in treatment) whether you should continue to take Tramadol Capsules and at what dose.
If you have the impression that the effect of Tramadol Capsules is too strong or too weak, talk to your doctor or pharmacist.

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
You should not suddenly stop taking this medicine unless your doctor tells you to. If you want to stop taking your medicine, discuss this with your doctor first, particularly if you have been taking it for a long time. Your doctor will advise you when and how to stop, which may be by lowering the dose gradually to reduce the chance of developing unnecessary side effects (withdrawal symptoms).
If you stop taking the capsules you may develop agitation, anxiety, nervousness, panic attacks, difficulty sleeping, tremor, over-activity, pins or 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, this medicine can cause side effects, although not everybody gets them.

Contact your doctor at once if you experience:
• an allergic reaction: itching, skin rash, 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, dizziness, 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, diarrhoea, retching and bloating.
• Rare (less than 1 in 1,000 users): extreme sense of wellbeing (euphoria), false sense of unenesses (dysphoria), confusion, hallucinations (sensing things that are not real), altered mental state (deltirium), 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), sleep 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

3 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 via wastewater or household waste. Ask your pharmacist how to dispose of medicines you 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 (E132). 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 30 and 100.
Marketing Authorisation Holder and Manufacturer
Actavis, Barnstaple, EX32 8NS, UK
Date of revision: July 2018

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