Tramadol hydrochloride
50mg capsules

Tramadol capsules are sometimes used along with other medicines. These include medicines for

- irritable bowel syndrome
- fibromyalgia
- restless legs syndrome

Other medicines and Tramadol capsules

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.
- vincristine (for gastric ulcers).
- ketoconazole or erythromycin (for infections).
- cimetidine (for gastric ulcers).
- amitriptyline or lofepramine).
- warfarin (for thinning the blood).
- medications to treat depression (including fluoxetine, paroxetine, amitrplyline or tafenoramine).
- medications 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.

Pregnancy and breast-feeding

Do not take Tramadol capsules if you are pregnant. If you are pregnant or breastfeeding, 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, you should stop breast-feeding.

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.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine
  - 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.

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.
  - Older people above 75 years: the excretion of tramadol may be delayed. If this applies to you, your doctor may recommend prolonging the dosage interval.
  - 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 in 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 or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

If you forget to take the capsules
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 no longer use. These measures will help to protect the environment.

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.

The recommended dose is one or two capsules three to four times a day. To be taken for as long as prescribed by your doctor.

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

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 no longer use. These measures will help to protect the environment.

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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: May 2018

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