Tramadol hydrochloride 50mg capsules

Please tell your doctor about all other medicines you are taking, and follow your doctor’s dose recommendation closely. It could be harmful to inform him or her to be aware of the other medicines you are taking. Contact your doctor when experiencing such symptoms.

The risk of side effects increases,
- if you are taking medicines which may cause convulsions (Fns), 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 are suitable for you.
- if you are taking certain antidepressants. Tramadol capsules may interact with these medicines and you may experience symptoms such as involuntaries, 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, pethidime, buprenorphine, nalorphine and pentaizone.
- medicines which slow your reactions and breathing down. carbamazepine (for epilepsy or nerve pain).
- sleeping tablets.
- medicines for gout (colchicine).
- loratadine or erythromycin (for infections).
- pseudoephedrine or phenylephrine (for colds). warfarin (for thinning the blood).
- medicines to treat depression (including fluoxetine, paroxetine, amitriptyline or fluvoxamine).
- 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 more 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, breast-feeding and fertility
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.
There is very little information regarding the safety of tramadol in human pregnancy. Therefore you should not use Tramadol if you are pregnant. Chronic use during pregnancy may lead to withdrawal symptoms in newborns.

Tramadol is excreted into breast milk. For this reason, you should not take Tramadol more than once during breast-feeding, or alternatively, if you take Tramadol more than once during breast-feeding, you should stop breast-feeding.

Based on human experience tramadol is suggested not to influence female or male fertility.

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 drowsy.
- Do not drive while taking this medicine until you know how it affects you.
- Do not drive if you feel that you are affected by the medicine.

The risk of side effects increases,
- if you drive or operate machinery while taking this medicine.
- if you are taking other medicines that may affect your driving ability.

If you have any further questions, ask your doctor, pharmacist or nurse.
This includes any possible side effects not listed in the leaflet. See section 4.
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 time each day.

Doses:

The dose 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 dose is one or two capsules at first, then one to two capsules every 4–6 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. If this applies to you, your doctor may recommend prolonging the dosing interval.
- Patients with liver or kidney impairment: the recommended dose is one to two capsules every 12 hours. Patients with severe liver or kidney insufficiency should not take Tramadol capsules. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosing 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 Tramadol Capsules than you should

If you have taken an additional dose by mistake, this will generally have no negative effects. You should take your next dose as prescribed. If you or someone else should swallow a lot of Tramadol at the same time, you should go to hospital or call a doctor straight away. Signs of an overdose include very small pupils, being very drowsy, being unconscious, fits and breathing difficulties or shallow breathing.

If you forget to take Tramadol Capsules

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

If you stop taking Tramadol Capsules

If you interrupt or finish treatment with Tramadol too soon, pain is likely to return. If you wish to stop treatment on account of unpleasant effects, please tell your doctor. 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).

Generally there will be no after effects when treatment with Tramadol is stopped. However, on rare occasions, people who have been taking Tramadol for some time may feel unwell if they abruptly stop taking them. They may feel anxious or upset, or become very drowsy or have difficulty in concentrating. These unpleasant effects usually subside if you take Tramadol again and then reduce the dose gradually. If you experience any of these complaints after stopping treatment with Tramadol, please consult your doctor.

Possible side effects

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

Very common
• headaches, drowsiness, fatigue, constipation, dry mouth
• undergoing nausea (may affect up to 1 in 10 people):
- allergic reactions (may affect less than 1 in 10,000 people):
  •  liver enzyme increased
  •  psychological complaints may appear after treatment with Tramadol. Their intensity and nature may vary according to the patient’s personality and length of therapy. These may appear as a change in mood (mostly high spirits, occasionally irritated mood), changes in activity (usually suppression, occasionally increase) and decreased cognitive and sensory perception (being less aware and less able to make decisions, which may lead to errors in judgement).
• drug dependence may occur. If treatment is stopped abruptly, signs of withdrawal may appear (see If you stop taking Tramadol).
• blurred vision, excessive dilation of the pupils (mydriasis), constriction of the pupil (miosis).
• slow breathing, shortness of breath (dyspnoea).
• worsening of asthma has been reported; however it has not been established whether it was caused by tramadol. If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down.
• weak muscles.
• passing urine with difficulty or pain, passing less urine than normal (dysuria).
• increased blood sugar level.

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.yellowcard.gov.uk or search for MAH 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.

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.

Contents of the pack and the other information

What Tramadol capsules contain

- The active substance is tramadol hydrochloride.
- The other ingredients are pregabaline stearate, 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

Accord Barnstaple, EX32 8NS, UK

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Tramadol Hydrochloride Capsules

50mg x 30s, 100s (UK)

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Dimensions: 148x210 (Reel Fed)

Component: 50mg x 30s, 100s (UK)

Pharmaceutical: 7810

Date Sent: 15/08/19

Technologist: T. Hull

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