Tramadol hydrochloride 50mg capsules

Please tell your doctor about all the other 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 constipation (e.g. certain antiparkinsonian or anti-epileptic drugs).
-  if you are taking other medicines that may cause constipation.

The risk of side effects may increase if you take:
-  other medicines which include strong pain killers such as morphine, pethidine, buprenorphine, nalbuphine and pentazocine.
-  medicines which slow your reactions and breathing down.
-  any opioid medicines which include strong painkillers such as morphine, pethidine, buprenorphine, nalbuphine and pentazocine.
-  any other medicine.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the leaflet. See section 4.

Do not drive while taking this medicine until you know how it affects you. Do not drive or operate machinery if 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 at it may make you sleepy or dizzy.

Do not drive while taking this medicine if you know 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 and
-  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
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 to prevent 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 every 4 to 6 hours according to the severity of the pain.
  - Other pain: the recommended dose is one capsule every 4 to 6 hours.

- **Patients with liver or kidney impairment:** the recommended dose is one capsule every 12 hours.

- **Older people:** the recommended dose is one or two capsules every 4 to 6 hours.

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

**How long should you take Tramadol capsules?**

You should stop taking 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 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.

- If you should take a double dose, seek medical advice by telephone or hospital as soon as possible.

- If you are someone else swallowing a lot of a 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 sick, fall in blood pressure, fast heartbeat, collapse, unconsciousness, 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 take it 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 suddenly, pain is likely to return. If you wish to stop treatment on account of unpleasant effects, please tell your doctor.

You should not stop taking this medicine unless your doctor tells you to. If you want to stop 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 slower than 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 unsettle if they abruptly stop taking them. They may feel agitated, anxious, nervous or shaky. They may be hyperactive, have difficulty sleeping and have stomach or bowel disorders. Very few people may get convulsions, hallucinations, unusual perceptions such as itching, singing and numbness, and ringing in the ears (tinnitus). Further unusual CNS symptoms, i.e. confusion, delusions, change of perception of the own personality (depersonalisation), and change in perception of reality (hallucinations) and delusion of persecution (paranoia) may have been seen very easily. If you experience any of these complaints after stopping Tramadol, please consult your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**Possible side effects**

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

- **You should see a doctor immediately if you experience symptoms of an allergic reaction such as swollen face, tongue and/or throat, and/or difficulty swallowing or hives together with difficulties in breathing.**
- **The most common side effects during treatment with Tramadol are nausea and dizziness, which occur in more than 1 in 10 people.**

**Very common** (may affect more than 1 in 10 people):

- dizziness, feeling sick (nausea)

**Common** (may affect up to 1 in 10 people):

- headaches, drowsiness, fatigue, constipation, dry mouth, being sick (vomiting), sweating, (hyperhidrosis)

**Uncommon** (may affect up to 1 in 100 people):

- effects on the heart and blood circulation (pounding of the heart, fast heartbeat, feeling faint or collapsed). These adverse effects may particularly occur in patients in an upright position or under physical strain.
- urge to be sick (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating, diarrhoea)
- skin reactions (e.g. itching, skin rash)

**Rare** (may affect up to 1 in 1000 people):

- allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin and shock (sudden circulation failure) have occurred in very rare cases)
- slow heart beat
- increased blood pressure
- abnormal sensations (e.g. pins and needles), trembling, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), speech disorders.
- Epileptic fits have occurred mainly at high doses of tramadol or when tramadol was taken at the same time as other medicines which may induce fits.
- changes in appetite
- hallucination, confusional state, sleep disorders, delirium, anxiety and nightmares
- psychological complaints may appear after treatment with Tramadol. Then intensity and nature may change (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 when 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 the medicines that depresses brain function are taken at the same time, breathing may slow down.
- weakness
- passing urine with difficulty or pain, passing less urine than normal (dysuria).

**Very rare** (may affect up to 1 in 10,000 people):

- liver enzyme increased

**Not known** (frequency cannot be estimated from the available data):

- decrease in 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.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.

**How to store Tramadol capsules**

Keep out of the sight and reach of children.

Do not store above 37°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 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 black (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 1NS, UK

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