

Tramadol Hydrochloride 50mg Effervescent Tablets

Read all of this leaflet carefully before you start using this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1 What this medicine is and what is it used for

Tramadol Hydrochloride is a pain reliever belonging to a group of medicines called opioids.

Opioids work by imitating the action of naturally occurring pain-reducing chemicals in the body called endorphins. They do this by combining with the opioid receptors in the brain and spinal cord. This blocks the transmission of pain signals sent by the nerves to the brain. Therefore, even though the cause of the pain may remain, less pain is actually felt.

Tramadol is used to treat moderate to severe pain.

2 What you need to know before you take Tramadol

Do not take Tramadol if:

- You are allergic (hypersensitive) to Tramadol, opioids or any of the other ingredients of this medicine (see section 6 "Contents of the pack and other information")
- You have had enough alcohol to make you drunk
- You have taken other medicines such as sleeping medicines (hypnotics), pain-relievers (analgesics), other opioids or psychotropic drugs (any drug capable of affecting the mind, emotions and behaviour) (see "Other medicines and Tramadol" section)
- You are taking or have taken in the last two weeks, medicines used to treat depression called MonoAmine Oxidase Inhibitors (MAOIs) (see "Other medicines and Tramadol" section)
- You have epilepsy and it is not adequately controlled by treatment
- It is for use in the treatment of drug withdrawal symptoms (see "Warnings and precautions" section)
- You suffer from phenylketonuria (an inherited disorder where the body is unable to break down a substance called phenylalanine (see "Tramadol Effervescent Tablets contains lactose and sodium and aspartame" section)

Warnings and precautions

Talk to your doctor before taking Tramadol:

- As using Tramadol may lead to developing withdrawal symptoms (see section 3 "If you stop taking Tramadol..."). Because of this, you should be reviewed regularly as to how long you need to continue your treatment
- If you are using Tramadol long-term, as you may become tolerant to Tramadol (where Tramadol becomes less effective in your treatment) or you may develop a mental and/or physical reliance (dependence) on Tramadol. If you have a tendency for drug abuse (misuse) or dependence, your treatment should be for short periods and under strict medical supervision
- If you are reliant (dependent) on opioids, as Tramadol is **not** a suitable substitute as it cannot help with morphine withdrawal symptoms
- If you suffer from:
 - o A head injury, reduced consciousness or a rise in pressure inside the skull that can result from or cause brain injury (increased intracranial pressure)
 - o A sensitivity to opiates
 - o Shock (pale face, cold/clammy skin, fast/shallow breathing, rapid/weak pulse, yawning, sighing and in extreme cases unconsciousness)
 - o Disorders of the respiratory centre (control of breathing) or respiratory function (ability to breathe)
 - o Severe impairment of liver and/or kidney function
- If you have a history of epilepsy or are prone to seizures, as the risk of fits (convulsions) may be increased if your dose of Tramadol exceeds the maximum daily dose limit of 400mg or if you are taking Tramadol together with medicines which lower the body's seizure threshold (see "Other medicines and Tramadol")
- If you are taking CNS (Central Nervous System) depressants, medicines used to treat anxiety and sleep disorders (see "Other medicines and Tramadol") as there is a possibility of developing respiratory depression (where your breathing becomes slower or weaker than usual)
- As use of Tramadol should be avoided if you are due to have a general anaesthetic using nitrous oxide or enflurane as it may enhance intraoperative recall (becoming conscious during a surgical procedure performed under general anaesthetic and subsequently have a recall of these events)

Other medicines and Tramadol:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Medicines which **may interact with or be affected by** Tramadol:

- MonoAmine Oxidase Inhibitors (MAOIs),

medicines used to treat depression such as moclobemide. Tell your doctor if you have taken one in the past 2 weeks

- CNS depressants, medicines used to treat anxiety and sleep disorders such as valium
- Carbamazepine, a medicine used to treat and prevent fits [seizures] (anticonvulsant)
- Selective Serotonin Re-uptake Inhibitors (SSRIs), medicines used to treat depression such as citalopram
- Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs), medicines used to treat mood and nerve disorders such as venlafaxine
- Tricyclic antidepressants, medicines used to treat depression such as amitriptyline
- Antipsychotics, medicines used to treat mood disorders such as lithium
- Medicines which lower the body's seizure threshold e.g. bupropion, mirtazapine, tetrahydrocannabinol
- Buprenorphine, nalbuphine, pentazocine, opioid analgesic medicines used to treat severe pain
- Coumarin derivatives e.g. warfarin, a medicine used to thin the blood (anticoagulant)
- Ketoconazole, a medicine used to treat fungal infections (antifungal)
- Erythromycin, a medicine used to treat bacterial infections (antibiotic)
- Ondansetron, a medicine used to prevent feeling and being sick [nausea and vomiting] (5HT 3-receptor antagonist)

Taking Tramadol with food and drink and alcohol

During treatment with Tramadol, it is recommended not to drink alcohol.

Pregnancy and Breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy:

- Tramadol should **not** be used during pregnancy.
- Babies born to mothers who took Tramadol long-term during pregnancy may develop withdrawal symptoms.

Breast-feeding:

- If you are breast-feeding, Tramadol should not be taken as Tramadol is passed into breast milk.
- However, if you take a single dose of Tramadol it is not usually necessary to stop breast-feeding.

Driving and using machines

Tramadol may cause drowsiness or dizziness. This is more likely to occur if you drink alcohol or are taking CNS depressants or psychotropic drugs (any drug capable of affecting the mind, emotions and behaviour) (see "Other medicines and Tramadol"). If any of these symptoms are experienced, it may be necessary to avoid driving or operating machinery or pursuing any activity in which full attention is required.

This 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:
 - o The medicine has been prescribed to treat a medical or dental problem and
 - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - o 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.

Tramadol Effervescent Tablets contains lactose and sodium and aspartame

- If you have been told by your doctor that you have an intolerance to some sugars (**lactose**) contact your doctor before taking this medicine.
- If you have been told by your doctor to stay on **low sodium diet**, contact your doctor before taking this medicine.
- If you suffer from **phenylketonuria**, an inherited disorder where the body is unable to break down a substance called phenylalanine contact your doctor before taking this medicine as it contains aspartame, a source of phenylalanine

3 How to take Tramadol

Always take Tramadol exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- The tablets are to be taken by dissolving in a glass of water and drinking all the liquid.

The dose of Tramadol should be adjusted according to the intensity of your pain and your individual pain sensitivity. The lowest possible dose should be taken.

Adults and children aged 12 years and over:

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