

Package leaflet: Information for the patient

Tramadol hydrochloride/Paracetamol 37.5 mg/325 mg Film-coated Tablets

tramadol hydrochloride/paracetamol

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or 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.

What is in this leaflet

1. What Tramadol hydrochloride/Paracetamol is and what it is used for
2. What you need to know before you take Tramadol hydrochloride/Paracetamol
3. How to take Tramadol hydrochloride/Paracetamol
4. Possible side effects
5. How to store Tramadol hydrochloride/Paracetamol
6. Contents of the pack and other information

1. What Tramadol hydrochloride/Paracetamol is and what it is used for

Tramadol hydrochloride/Paracetamol is a combination of two analgesics, tramadol and paracetamol, which act together to relieve your pain.

Tramadol hydrochloride/Paracetamol is used for the treatment of moderate to severe pain when your doctor decides that a combination of tramadol and paracetamol is necessary.

Tramadol hydrochloride/Paracetamol should only be taken by adults and adolescents 12 years of age and over.

2. What you need to know before you take Tramadol hydrochloride/Paracetamol

Do not take Tramadol hydrochloride/Paracetamol:

- if you are allergic to paracetamol, tramadol or any of the other ingredients of this medicine (listed in section 6)
- in cases of acute alcohol poisoning
- if you are taking sleeping pills, pain relievers or medicines that affect mood and emotions
- if you are taking medicines called monoamine oxidase inhibitors (MAOIs) or have taken MAOIs in the last 14 days before treatment with Tramadol hydrochloride/Paracetamol. MAOIs are used in the treatment of depression or Parkinson's disease
- if you have a severe liver disorder
- if you suffer from epilepsy that is not adequately controlled by your current medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tramadol hydrochloride/Paracetamol:

- if you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Tramadol hydrochloride/Paracetamol')
- if you take other medicines containing paracetamol or tramadol
- if you have severe kidney problems. In this case the use of Tramadol hydrochloride/Paracetamol is not recommended
- if you have liver problems or liver disease or if you notice your eyes and skin turning yellow. This may suggest jaundice or problems with your bile ducts

- if you have severe difficulties in breathing, for example asthma or severe lung problems
- if you are, or have ever been, addicted to or dependent on any medicine (for example morphine)
- if you have recently suffered from a head injury, shock or severe headaches associated with vomiting (being sick)
- if you have been experiencing changes in consciousness (e.g. falling unconscious for an unknown reason)
- if you have epilepsy or have previously experienced fits or seizures
- if you take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine

Tramadol must not be taken as a substitute therapy in opioid-dependent patients, since it does not suppress morphine withdrawal symptoms.

There is a small risk that you may experience a so-called serotonin syndrome that can occur after having taken tramadol in combination with certain antidepressants or tramadol alone. Seek medical advice immediately if you have any of the symptoms related to this serious syndrome (see section 4 'Possible side effects').

Sleep-related breathing disorders

Tramadol hydrochloride/Paracetamol can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Tramadol is transformed in the liver by an enzyme. Some people have a variation of this enzyme and this can affect people in different ways. In some people, they may not get enough pain relief but other people are more likely to get serious side effects. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

During treatment

If you are going to have an anaesthetic, tell your doctor or dentist that you are taking Tramadol hydrochloride/Paracetamol.

Extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels). If you have these symptoms, contact your doctor, who will decide if you need to take hormone supplement.

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.

Other medicines and Tramadol hydrochloride/Paracetamol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tramadol hydrochloride/Paracetamol must not be taken in combination with:

- other medicines containing paracetamol or tramadol, so that you do not exceed the maximum daily doses
- MAOIs (used in the treatment of depression or Parkinson's disease), since this may cause serotonergic syndrome. Symptoms of serotonergic syndrome include diarrhoea, increased heartbeat, sweating, trembling, confusion and even coma. If you have recently taken an MAOI, you should wait 14 days before taking Tramadol hydrochloride/Paracetamol.

Tramadol hydrochloride/Paracetamol is not recommended with the following medicines as it may affect how well they work:

- carbamazepine (a medicine used to treat epilepsy or some types of pain)
- opioid-type painkillers (buprenorphine, nalbuphine, pentazocine).

Tramadol hydrochloride/Paracetamol may increase the risk of side effects if you also take the following medicines:

- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.
- certain antidepressants or triptans (used for migraine). Tramadol hydrochloride/Paracetamol may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects').
- barbiturate medicines (such as phenobarbital), tranquilisers, sleeping pills and pain relievers such as morphine or codeine (also as cough medicines and substitutive treatments), baclofen (a muscle relaxant), medicines used to lower blood pressure, antidepressants, antipsychotics, medicines to treat allergies or thalidomide (a medicine used to treat cancer of the bone marrow). You may feel drowsy or faint, or experience shallow breathing. If this happens, tell your doctor
- medicines which may cause convulsions (fits), such as certain antidepressants, antipsychotics, tetrahydrocannabinol (a constituent of cannabis) or bupropion (to help stop smoking). The risk of having a fit may increase if you take Tramadol hydrochloride/Paracetamol at the same time. Your doctor will tell you whether Tramadol hydrochloride/Paracetamol is suitable for you
- Concomitant use of Tramadol hydrochloride/Paracetamol 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 hydrochloride/Paracetamol 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
- vitamin K antagonists such as warfarin or other anticoagulants, e.g. phenprocoumon (used for blood thinning). The effectiveness of such medicines may be altered and bleeding may occur. Any prolonged or unexpected bleeding should be reported to your doctor immediately.

The effectiveness of Tramadol hydrochloride/Paracetamol may be altered if you also take the following medicines:

- metoclopramide, domperidone or ondansetron (medicines used to treat nausea and vomiting)
- cholestyramine (medicine used to reduce cholesterol in the blood)
- ketoconazole or erythromycin (medicines used against infections).

Tramadol hydrochloride/Paracetamol with drink and alcohol

Do not drink alcohol during your treatment with Tramadol hydrochloride/Paracetamol, as you may feel drowsy.

Pregnancy, breast-feeding and fertility

As Tramadol hydrochloride/Paracetamol contains tramadol, do not take this medicine during pregnancy.

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

Based on human experience, tramadol is not expected to have an effect on female or male fertility. No data on the effect of the combination of tramadol and paracetamol on fertility are available.

Driving and using machines

If you feel drowsy or dizzy while taking Tramadol hydrochloride/Paracetamol you must not drive or use 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:
 - 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 hydrochloride/Paracetamol contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Tramadol hydrochloride/Paracetamol

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

Adults and adolescents 12 years of age and older

- The recommended dose is to start with 2 tablets, unless otherwise prescribed by your doctor.
- If required, further doses may be taken, as instructed by your doctor.
- The shortest time between doses must be at least 6 hours.
- 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.
- Do not take more than 8 tablets per day.

Older patients

In older patients (above 75 years) the excretion of tramadol may be delayed. If this applies to you, your doctor may recommend prolonging the dosage interval.

Severe liver or kidney disease (insufficiency)/dialysis patients

Patients with severe liver and/or kidney insufficiency should not take Tramadol hydrochloride/Paracetamol. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

Use in children under 12 years of age

Tramadol hydrochloride/Paracetamol is not recommended for use in children under 12 years of age.

Method of administration

- You have to take the tablets orally.
- Swallow the tablets whole, with a sufficient quantity of liquid. The tablets must not be broken or chewed.
- Tramadol hydrochloride/Paracetamol can be taken with or without food.

Duration of treatment

Take Tramadol hydrochloride/Paracetamol for as short a time as possible and no longer than your doctor has told you. If you think that the effect of Tramadol hydrochloride/Paracetamol is too strong (you feel very drowsy or have difficulty breathing) or too weak (you do not have enough pain relief), contact your doctor.

If you take more Tramadol hydrochloride/Paracetamol than you should

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

In case of an overdose, you may experience nausea (feeling sick), blurred vision/difficulty focusing, vomiting, loss of appetite, stomach pain or discomfort, serious circulation failure (cardiovascular collapse), loss of consciousness including coma, convulsions, shallow breathing which can cause your breathing to stop (respiratory arrest), and pale skin.

Liver damage may appear 12 to 48 hours after ingestion. In severe poisoning, liver failure may lead to severe brain disease (encephalopathy), coma and death. Acute kidney failure may develop, even in the absence of severe liver damage. Cardiac arrhythmias (irregular heartbeat) and pancreatitis (inflammation of the pancreas) have also been reported.

If you forget to take Tramadol hydrochloride/Paracetamol

If you forget to take this medicine you can skip the missed dose and continue the treatment as normal, or you can take the missed tablet but you must keep a 6 hour interval between doses.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Tramadol hydrochloride/Paracetamol

Do not stop taking this medicine without consulting 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 hydrochloride/Paracetamol is stopped.

Rarely, people who have been using a medicine containing tramadol may become dependent on it, making it hard to stop taking it. If you have been taking Tramadol hydrochloride/Paracetamol for some time and want to stop, contact your doctor because your body may have become used to Tramadol hydrochloride/Paracetamol.

People may:

- feel agitated, anxious, nervous or shaky
- be over active
- have difficulty sleeping
- have stomach or bowel disorders.

Very few people may also get:

- panic attacks
- hallucinations, unusual perceptions such as itching, tingling and numbness
- ringing in the ears.

If you experience any of these complaints after stopping Tramadol hydrochloride/Paracetamol, please contact your doctor.

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

4. Possible side effects

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

If you think you may have any of the following side effects, stop taking this medicine and contact your doctor or go to your nearest hospital emergency room immediately. These side effects may need medical attention:

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

- blood in the stools (your stools may be black and tarry or have fresh, red, blood on them)
- difficulty or pain when passing urine.

Rare (may affect up to 1 in 1,000 people)

- sudden signs of allergic reactions such as rash, itching or hives on the skin, swelling of the face, lips, tongue and other parts of the body, shortness of breath, wheezing or trouble breathing, low blood pressure
- fits (seizures)
- shallow breathing
- extreme confusion, which may be associated with hallucinations (seeing, feeling or hearing things that are not there), increased or decreased activity and sleep problems (delirium).

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

- very rare cases of serious skin reactions have been reported.

Not known: frequency cannot be estimated from the available data:

- Serotonin syndrome, that can manifest as mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as fever, increase in heart rate, unstable blood pressure, involuntary twitching, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea) (see section 2 'What you need to know before you take Tramadol hydrochloride/Paracetamol').
- prolonged or unexpected bleeding, from the use of Tramadol hydrochloride/Paracetamol with medicines used to thin the blood (e.g. warfarin, phenprocoumon)
- changes in the levels of blood cells (seen on a blood test) with frequent infections (fever, severe chills, sore throat or mouth ulcers).

Other side effects include:

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

- dizziness, sleepiness
- nausea (feeling sick).

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

- confusion, mood changes (anxiety, nervousness, elation), sleep disorders
- headache, shaking
- vomiting (being sick), constipation, dry mouth, diarrhoea, stomach pain or discomfort, indigestion, wind (flatulence)
- sweating, itching.

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

- depression, hallucinations (seeing, feeling or hearing things that are not there), nightmares, memory loss
- involuntary muscle twitching, tingling, numbness or feeling of pins and needles in the limbs, ringing in the ears
- increase in pulse or blood pressure or heart rate
- disturbances of the electrical rhythm of the heart (arrhythmia)
- difficulty breathing
- difficulty in swallowing
- increased levels of liver enzymes (seen on a blood test)
- skin reactions (e.g. rash, hives)
- protein in the urine (seen on a urine test)
- shivering, hot flushes, chest pain.

Rare (may affect up to 1 in 1,000 people):

- drug dependence
- fainting, which may lead to collapse
- lack of coordination
- problems with speech
- blurred vision, small or large pupil.

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

- drug abuse.

Not known: frequency cannot be estimated from the available data:

- decrease in blood sugar level.

In addition, the following side effects have been reported by people using medicines that contain only tramadol or only paracetamol:

Rare (may affect up to 1 in 1,000 people):

- changes in appetite, muscle weakness.

Not known: frequency cannot be estimated from the available data:

- feeling faint when getting up from a lying or sitting position, slow heart rate
- changes in the levels of blood cells (seen on a blood test) with bleeding or bruising more easily than normal
- mood changes, changes in activity and changes in perception
- worsening of existing asthma.
- hiccups.

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.

5. How to store Tramadol hydrochloride/Paracetamol

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, bottle and blister foil after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Bottles: Use within 100 days of opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tramadol hydrochloride/Paracetamol contains

- The active substances are tramadol hydrochloride and paracetamol. Each film-coated tablet contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol.
- The other ingredients (excipients) are: Tablet core – maize starch, pregelatinised; povidone; crospovidone; stearic acid; silica, colloidal anhydrous; magnesium stearate. Film-coating – hypromellose 6cP; lactose monohydrate (see section 2 “Tramadol hydrochloride/Paracetamol contains lactose”); titanium dioxide (E171); macrogol 300; triacetin; iron oxide yellow (E172); macrogol 4000; hypromellose 15cP; hypromellose 3cP; hypromellose 50cP.

What Tramadol hydrochloride/Paracetamol looks like and contents of the pack

Tramadol hydrochloride/Paracetamol are light yellow, oblong film-coated tablets with “P/T” marked on one side of the tablet and “M” on the other.

Tramadol hydrochloride/Paracetamol are packed in blisters containing 2, 5, 10, 20, 30, 40, 50, 60, 90, 100 and 200 film-coated tablets, perforated unit dose blisters containing 20 x 1 and 60 x 1 film-coated tablet(s), bottles with child-resistant closures containing 100 film-coated tablets and bottles with screw cap closures containing 500 film-coated tablets (dispensing pack).

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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