

Package Leaflet: Information for the patient

Tramadol/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/Paracetamol is and what it is used for
2. What you need to know before you take Tramadol/Paracetamol
3. How to take Tramadol/Paracetamol
4. Possible side effects
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1. What Tramadol/Paracetamol is and what is used for

Tramadol/Paracetamol is used to treat moderate to severe pain when your doctor recommends that a combination of tramadol hydrochloride and paracetamol is needed.

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

Do not take Tramadol/Paracetamol if you are allergic to tramadol, paracetamol 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 also taking medicines called monoamine oxidase inhibitors (MAOIs) or have taken MAOIs in the last 14 days before treatment with Tramadol/Paracetamol. MAOIs are used in the treatment of depression or Parkinson's disease.
- if you have a severe liver disorder.
- if you have epilepsy that is not adequately controlled by your current medicine.

Warnings and precautions

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

- take other medicines containing paracetamol or tramadol
- have liver problems or disease as your eyes and skin may turn yellow, which may suggest jaundice.
- have kidney problems
- have severe difficulties in breathing, for example asthma or severe lung problems.
- have epilepsy or have already experienced fits or seizures
- have recently suffered from a head injury, shock or severe headaches associated with vomiting (being sick).
- are dependent on any medicine (for example morphine)
- take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine
- are going to have an anaesthetic (tell your doctor or dentist that you are taking Tramadol/Paracetamol)

- suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see “Other medicines and Tramadol/Paracetamol”)

Prolonged or frequent use of pain relieving medication can cause headaches, or make them worse. If this happens, you must not increase the dose of this medicine. It is important that you speak to your doctor for advice about stopping treatment.

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/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.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking tramadol/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.

Other medicines and Tramadol/Paracetamol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This medicine contains paracetamol. Do not take any other paracetamol-containing products.

Please inform your doctor or pharmacist if you are taking:

-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.

Do not exceed the maximum daily doses of paracetamol or tramadol from this or other medicines.

Do not take Tramadol/Paracetamol with MAOIs (see section ‘Do not take Tramadol/Paracetamol’)

Tramadol/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) buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers).

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

- triptans (used for migraine) or certain antidepressants, Tramadol/Paracetamol may interact with these medicines and you may experience serotonin syndrome (see section 4 “Possible side effects”)
- tranquilizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), baclofen (a muscle relaxant), medicines used to lower blood pressure, antidepressants or medicines to treat allergies. Check with your doctor if you feel drowsy or feel faint.

- antidepressants, anaesthetics, medicines that affect the state of mind or bupropion (used to help stop smoking). The risk of having a fit may increase. Your doctor will tell you whether Tramadol/Paracetamol is suitable for you.
- warfarin or phenprocoumon (for blood thinning). The effectiveness of such medicines may be altered and bleeding may occur (see section 4).

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

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

Concomitant use of Tramadol/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/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.

Tramadol/Paracetamol with food, drink and alcohol

Do not drink alcohol while you are taking Tramadol/Paracetamol, as you may feel drowsy.

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 or pharmacist for advice before taking this medicine.

Pregnancy

Do not take Tramadol/Paracetamol while you are pregnant. Check with your doctor if you become pregnant during treatment with Tramadol/Paracetamol and before taking any further tablets.

Breast-feeding

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

Driving and using machines

If you feel drowsy while taking Tramadol/Paracetamol, do not drive, use tools or use machinery.

Tramadol/Paracetamol contains lactose monohydrate

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

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Tramadol/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.

Swallow the tablets whole with sufficient liquid.

Do not break or chew the tablets.

Take Tramadol/Paracetamol for as short a time as possible and no longer than your doctor has told you.

Adults and adolescents over 12 years:

The recommended dosage 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.

Do not take more than 8 tablets per day.

Your doctor may increase the time between doses if:

- you are older than 75 years
- you have kidney problems
- you have liver problems.

Children under 12 years of age

Not recommended

If you think that the effect of Tramadol/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.

The maximum daily dose is 8 tablets per day (equivalent to 300 mg of tramadol and 2600 mg of paracetamol). Do not exceed this dose from this or other medicines.

If you take more Tramadol/Paracetamol than you should

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

If you forget to take Tramadol/Paracetamol

If you forget to take the tablets, pain is likely to return. If you forget to take a dose, take it as soon as you remember, unless it is nearly time for your next dose. Then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Tramadol/Paracetamol

Generally, there will be no after-effects when treatment with Tramadol/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/Paracetamol for some time and want to stop, contact your doctor because your body may have become used to Tramadol/Paracetamol and your doctor may want to reduce your dose gradually.

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/Paracetamol, please contact your doctor. Other side effect information is listed in section 4.

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.

Stop taking Tramadol/Paracetamol Tablets and see a doctor or go to a hospital straight away if any of the following occurs:

rarely cases of skin rash, indicating an allergic reaction, may develop with sudden swelling of the face and neck, difficulties breathing or drop of blood pressure and fainting. If this happens to you, stop treatment. Do not take the medicine again.

- prolonged or unexpected bleeding, from the use of Tramadol/Paracetamol with medicines used to thin the blood (e.g. warfarin, phenprocoumon).

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

- hallucinations (hearing, seeing or sensing things that are not really there)
- Difficulty breathing.

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

- fits
- transient loss of consciousness (syncope).

Other side effects:

If any of the following side effects get serious, contact your doctor or pharmacist:

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

- nausea
- dizziness, drowsiness.

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

- vomiting (being sick), digestion problems (constipation, flatulence, diarrhoea), stomach pain, dry mouth
- itching, sweating
- headache, shaking,
- confusion, sleep disorders, mood changes (anxiety, nervousness, feeling of high spirits).

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

- increase in pulse or blood pressure increase in pulse or blood pressure, heart rate or heart rhythm disorders
- difficulty or pain on passing water/protein in the urine
- skin reactions (for example rashes, hives)
- tingling, numbness or feeling of pins and needles in the limbs, ringing in the ears, involuntary muscle twitching
- depression, nightmares, memory lapses,
- difficulty swallowing, blood in the stools
- shivering, hot flushes, pain in the chest
- raised liver enzymes (shown in blood tests)

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

- uncoordinated movements
- addiction
- blurred vision

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

- abuse

Very rare cases of serious skin reactions have been reported

Unknown (frequency cannot be estimated from the available data):

- decrease in blood sugar level
- hiccups
- 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/Paracetamol).

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

- feeling faint when getting up from a lying or sitting position, slow heart rate, fainting
- changes in appetite
- muscle weakness, slower or weaker breathing
- mood changes, changes in activity, changes in perception
- worsening of existing asthma
- nose bleeds or bleeding gums, which may result from a low blood platelet count.

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 HPRAs Pharmacovigilance Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tramadol/Paracetamol

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

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

This medicinal product does not require any special storage conditions.

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/Paracetamol contains

- The active substances are: 37.5 mg tramadol hydrochloride and 325 mg paracetamol.
- The other ingredients are:
Tablet core:
Pre-gelatinised Maize Starch
Stearic acid
Crospovidone
Povidone (Plasdone K29-32)
Maize Starch

Croscarmellose sodium
Microcrystalline cellulose
Magnesium stearate (vegetable)
Film-coating:
Opadry yellow II OYL 22903 (Lactose monohydrate, Hypromellose 15cP, Titanium dioxide,
Macrogol/PEG 4000, Talc, Iron oxide yellow)

What Tramadol/Paracetamol looks like and contents of the pack

6.4 mm x 15.5mm, yellow, oblong, biconvex, film coated tablet with "T" on one side

Tramadol/Paracetamol is available in blister packs of 2, 10, 20, 30, 40, 50, 60, 70, 80, 90 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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