

PACKAGE LEAFLET: INFORMATION FOR THE USER
Tramadol/Paracetamol Teva 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. Do not pass it on to others. It may harm them, even if their symptoms 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 TRAMADOL/PARACETAMOL TEVA IS AND WHAT IT IS USED FOR

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

Tramadol/Paracetamol Teva is intended for use in the treatment of moderate to severe pain when your doctor recommends that a combination of tramadol and paracetamol is needed.

Tramadol/Paracetamol Teva should only be taken by adults and adolescents over 12 years.

2. BEFORE YOU TAKE TRAMADOL/PARACETAMOL TEVA

Do not take Tramadol/Paracetamol Teva

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

Warnings and precautions Talk to your doctor or pharmacist before taking Tramadol/Paracetamol Teva

- if you take other medicines containing paracetamol or tramadol;

- 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 kidney problems;
- if you have severe difficulties in breathing, for example asthma or severe lung problems;
- if you have epilepsy or have already experienced fits or seizures;
- if you have recently suffered from a head injury, shock or severe headaches associated with vomiting;
- if you are dependent on any medicines including those used to relieve pain, for example morphine;
- if you take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine;
- if you are going to have an anaesthetic. Tell your doctor or dentist that you are taking Tramadol/Paracetamol Teva.

If any of the above-mentioned points applied to you in the past or applies to you while you are taking Tramadol/Paracetamol Teva, please make sure your doctor knows. He/she can then decide whether you should continue to use this medicine.

Other medicines and Tramadol/Paracetamol Teva

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

Important: This medicine contains paracetamol and tramadol. Tell your doctor if you are taking any other medicine containing paracetamol or tramadol, so that you do not exceed the maximum daily doses.

You **must not** take Tramadol/Paracetamol Teva together with monoamine oxidase inhibitors (“MAOIs”) (see section “Do not take Tramadol/Paracetamol Teva”).

Tramadol/Paracetamol Teva is not recommended to be taken with the following:

- carbamazepine (a medicine commonly used to treat epilepsy or some types of pain such as severe pain attacks in the face called trigeminal neuralgia),
- buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers). The pain-relieving effect may be reduced.

The risk of side effects increases:

- if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk having a fit may increase if you take Tramadol/Paracetamol Teva at the same time. Your doctor will tell you whether Tramadol/Paracetamol Teva is suitable for you.
- if you are taking certain antidepressants. Tramadol/Paracetamol Teva may interact with these medicines and you may experience symptoms such as involuntary, 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.

The risk of side effects increases, if you also take:

- tranquillizers, 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. You may feel drowsy or feel faint. If this happens, tell your doctor.
- anaesthetics, neuroleptics (medicines that affect the state of mind) or bupropion (to help stop smoking). The risk of having a fit may increase. Your doctor will tell you whether Tramadol/Paracetamol Teva is suitable for you.
- warfarin or phenprocoumon (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/Paracetamol Teva may be altered if you also take:

- metoclopramide, domperidone or ondansetron (medicines for treatment of nausea and vomiting),
- cholestyramine (medicine to reduce cholesterol in the blood),

- ketoconazole or erythromycin (medicines against infections).

Your doctor will tell you which medicines are safe to take with Tramadol/Paracetamol Teva.

Taking Tramadol/Paracetamol Teva with food, drink and alcohol

Tramadol/Paracetamol Teva may make you feel drowsy. Alcohol may make you feel more drowsy, so it is best not to drink alcohol while you are taking Tramadol/Paracetamol Teva.

Pregnancy and breast-feeding

As this medicine contains tramadol, you should not take this medicine during pregnancy. If you become pregnant during treatment with Tramadol/Paracetamol Teva, please consult your doctor before taking any further tablets.

Small amounts of tramadol may pass into the breast-milk. Therefore you should not take this medicine during 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 any medicine.

Driving and using machines

Tramadol/Paracetamol Teva may make you feel drowsy and this may affect your ability to drive, or use tools and machines, safely.

3. HOW TO TAKE TRAMADOL/PARACETAMOL TEVA

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

You should take Tramadol/Paracetamol Teva for as short a time as possible. The use in children below the age of 12 years is not recommended.

Unless otherwise prescribed by your doctor, the usual starting dose for adults and adolescents over 12 years is 2 tablets.

If required, further doses may be taken, as recommended by your doctor. The shortest time between doses must be at least 6 hours.

Do not take more than 8 Tramadol/Paracetamol Teva Film-coated Tablets per day.

Do not take Tramadol/Paracetamol Teva more often than your doctor has told you.

Your doctor may increase the time between doses

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

Use in children

The use in children below the age of 12 years is not recommended.

Method of administration:

The tablets are for oral use.

Swallow the tablets whole with sufficient liquid, they should not be broken or chewed.

If you think that the effect of Tramadol/Paracetamol Teva is too strong (i.e. you feel very drowsy or have difficulty breathing) or too weak (i.e. you have inadequate pain relief), contact your doctor.

If you take more Tramadol/Paracetamol Teva than you should

In such cases please contact your doctor or pharmacist immediately even if you feel well.

There is a risk of liver damage which may only show later.

If you forget to take Tramadol/Paracetamol Teva

If you forget to take the tablets, pain is likely to return. Do not take a double dose to make up for forgotten doses. Simply continue taking the tablets as before.

If you stop taking Tramadol/Paracetamol Teva

Generally there will be no after-effects when treatment with Tramadol/Paracetamol Teva is stopped. However, on rare occasions, people who have been taking tramadol for some time may feel unwell if they stop treatment abruptly (see section 4. "Possible Side Effects"). If you have been taking Tramadol/Paracetamol Teva for some time, you should talk to your doctor if you want to stop because your body may have become used to it.

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.

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

- nausea,
- dizziness, drowsiness.

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

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

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

- increase in pulse or blood pressure, heart rate or heart rhythm disorders,
- difficulty or pain on passing water,
- skin reactions (for example rashes, hives),
- tingling, numbness or feeling of pins and needles in the limbs, ringing in the ear, involuntary muscle twitching,
- depression, nightmares, hallucinations (hearing, seeing or sensing things that are not really there), memory lapses,
- difficulty swallowing, blood in the stools,
- shivering, hot flushes, pain in the chest,
- difficulty breathing,
- increase in liver enzymes (hepatic transaminases).

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

- fits, difficulties in carrying out coordinated movements,
- addiction,
- blurred vision.

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

- decrease in blood sugar level

The following are recognised side effects which have been reported by people using medicines that contain only tramadol or only paracetamol.

However, if you experience any of these while taking Tramadol/Paracetamol Teva, you should tell your doctor:

- 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.
- In some rare cases a 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 and see a doctor immediately. You must not take the medicine again.

- Very rare cases of serious skin reactions have been reported

In rare cases, using a medicine of the type of tramadol may make you become dependent on it, making it hard to stop taking it.

On rare occasions, people who have been taking tramadol for some time may feel unwell if they stop treatment abruptly. 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 also get panic attacks, hallucinations, unusual perceptions such as itching, tingling and numbness, and noise in the ears (tinnitus). If you experience any of these complaints after stopping Tramadol/Paracetamol Teva, please consult your doctor.

In exceptional cases blood tests may reveal certain abnormalities, for instance, low counts of blood platelets, which may result in nose bleeds or bleeding gums.

Use of Tramadol/Paracetamol Teva together with medicines used to thin the blood (e.g. phenprocoumon, warfarin) may increase the bleeding risk. Any prolonged or unexpected bleeding should be reported to your doctor immediately.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TRAMADOL/PARACETAMOL TEVA

Keep out of the reach and sight of children.

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

Discard the bottle 50 days after first opening

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Tramadol/Paracetamol Teva contains

- The active substances are tramadol hydrochloride and paracetamol. Each film-coated tablet contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol. Contains Paracetamol.
- The other ingredients are: tablet core: kollicoat IR coating [Macrogol poly(vinyl alcohol) grafted copolymer], pregelatinised maize starch, cellulose microcrystalline, sodium starch glycolate (type A), Hypromellose, magnesium stearate; film-coating: opadry II beige 85F97409: polyvinyl alcohol, titanium

dioxide (E171), macrogol, talc, iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172).

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

Tramadol/Paracetamol Teva film-coated tablets are peach coloured, capsule shaped, engraved with T37.5 on one side and A325 on the other side.

Tramadol/Paracetamol Teva comes in cartons with blister packs of 2, 10, 15, 20, 30, 40, 60, 90 and 120 tablets and bottles with 10 tablets and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorization Holder

Teva Pharma B.V.

Swensweg 5, 2031 GA Haarlem, The Netherlands

Manufacturer

Teva Pharmaceutical Works Private Limited Company

Pallagi út 13, 4042 Debrecen,

Hungary

Teva UK Ltd

Brampton Road, Hampden Park, Eastbourne,

East Sussex, BN22 9AG,

United Kingdom

TEVA Czech Industries s.r.o

Ostravska 29/305, 747 70 Opava-Komarov,

Czech Republic

Teva Pharma S.L.U.C/C, n. 4, Poligono Industrial Malpica, 50016 Zaragoza,

Spain

PLIVA Ljubljana d.o.o.

Pot k sejmišču 35, 1231 Ljubljana,

Slovenia

Teva Operations Poland Sp.z.o.o.

Mogilska 80, 31-546 Krakow

Poland

Teva Operations Poland Sp.z.o.o

Ul. Sienkeiwicza 25, 99-300 Kutno

Poland

Pliva Hrvatska d.o.o.

Prilaz baruna Filipovica 25

10000 Zagreb

Croatia

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Tramadol/Paracetamol Teva 37,5 mg/325 mg filmomhulde tabletten

Czech Republic, Iceland, Ireland, Slovenia, Spain: Tramadol/Paracetamol Teva 37.5 mg/325 mg film-coated tablets

France: TRAMADOL/PARACETAMOL TEVA

Netherlands: Tramadol HCl/Paracetamol 37,5/325 mg Teva
Portugal: Tramadol + Paracetamol Teva 37.5 mg/325 mg film-coated tablets
Poland, Romania: PADOLTEN 37.5 mg/325 mg film-coated tablets
United Kingdom: Tramadol hydrochloride/Paracetamol

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