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

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

Tramadol hydrochloride/Paracetamol 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 hydrochloride/Paracetamol should only be taken by adults and adolescents 12 years and older.

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

Do not take Tramadol hydrochloride/Paracetamol
- 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 hydrochloride/Paracetamol;
- 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
- 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 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 any of the above-mentioned points applied to you in the past or applies to you while you are taking Tramadol hydrochloride/Paracetamol, please make sure your doctor knows. He/she can then decide whether you should continue to use this medicine.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Tramadol/Paracetamol Teva: 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.

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 Teva 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.

Other medicines and Tramadol hydrochloride/Paracetamol
Please tell your doctor or pharmacist if you are taking or 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 hydrochloride/Paracetamol together with monoamine oxidase inhibitors ("MAOIs") (see section "Do not take Tramadol hydrochloride/Paracetamol").

Tramadol hydrochloride/Paracetamol 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.

Concomitant use of Tramadol/Paracetamol Teva 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 Teva 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.

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 hydrochloride/Paracetamol at the same time. Your doctor will tell you whether Tramadol hydrochloride/Paracetamol is suitable for you.
- certain antidepressants. Tramadol hydrochloride/Paracetamol may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects').
- 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.
- antidepressants, 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 hydrochloride/Paracetamol 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 hydrochloride/Paracetamol 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 hydrochloride/Paracetamol.

Tramadol hydrochloride/Paracetamol with food, drink and alcohol
Tramadol hydrochloride/Paracetamol may make you feel drowsy or dizzy. Alcohol may make you feel more drowsy, so it is best not to drink alcohol while you are taking Tramadol hydrochloride/Paracetamol.

Pregnancy, breast-feeding and fertility

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

Breast-feeding
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 Tramadol hydrochloride/Paracetamol more than once, you should stop 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.

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

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

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:

- 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 and
- 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.

3. How to take Tramadol hydrochloride/Paracetamol

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 hydrochloride/Paracetamol for as short a time as possible.

Unless otherwise prescribed by your doctor, the usual starting dose for adults and adolescents 12 years and older 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.

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 Tramadol hydrochloride/Paracetamol Film-coated Tablets per day.

Do not take Tramadol hydrochloride/Paracetamol 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 hydrochloride/Paracetamol 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 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.

If you forget to take Tramadol hydrochloride/Paracetamol
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 hydrochloride/Paracetamol

Generally there will be no after-effects when treatment with Tramadol hydrochloride/Paracetamol 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 hydrochloride/Paracetamol 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.

If you experience any of the following, stop treatment and see a doctor immediately. You must not take the medicine again.

Rare (may affect up to 1 in 1,000 people):
- skin rash, indicating an allergic reaction, with sudden swelling of the face and neck, difficulties breathing or drop of blood pressure and fainting.

Other reported side effects include:

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, increase of a certain protein in the urine (albuminuria),
- 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
- transient loss of consciousness (syncope)

Unknown frequency (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 hydrochloride/Paracetamol').

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 hydrochloride/Paracetamol, 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. 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 hydrochloride/Paracetamol, 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 hydrochloride/Paracetamol 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 or pharmacist. 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 out of the sight and reach 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.

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 are: tablet core: kollicoat IR coating [Macrogol poly(vinyl alcohol) grafted copolymer], pregelatinised maize starch, cellulose microcrystalline, sodium starch glycolate (type A), Hyprolose, 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 hydrochloride/Paracetamol looks like and contents of the pack
Tramadol hydrochloride/Paracetamol Film-coated Tablets are peach coloured, capsule-shaped, engraved with T37.5 on one side and A325 on the other side.
Tramadol hydrochloride/Paracetamol 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 UK Limited, Eastbourne, BN22 9AG, UK

Manufacturer
Pliva Hrvatska d.o.o. (Pliva Croatia Ltd.)
Prilaz baruna Filipovića 25,
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Croatia

or:

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