

Package leaflet: Information for the user
<Invented name> 37.5mg/325mg, 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 <Invented name> is and what it is used for
2. What you need to know before you take <Invented name>
3. How to take <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

1. What <Invented name> is and what it is used for

This medicine is a combination of two analgesics, tramadol and paracetamol, which act together to relieve your pain.

This medicine is intended for use in the treatment of moderate to severe pain when your doctor recommends that a combination of tramadol hydrochloride and paracetamol is needed.

This medicine should only be taken by adults and adolescents over 12 years.

2. What you need to know before you take <Invented name>

Do not take <Invented name>

- if you have had an allergic reaction (for instance skin rash, swelling of the face, wheezing or difficulty breathing) after taking 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 <Invented name>;
- if you suffer from a severe liver disorder;
- if you have epilepsy that is not adequately controlled on your current medicine.

Warnings and precautions

Talk to your doctor before taking <Invented name> if you:

- take other medicines containing paracetamol or tramadol;

- 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;
- 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;
- are dependent on any medicines including those used to relieve pain, 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 <Invented name>.

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

Children and adolescents

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

Other medicines and <Invented name>

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 <Invented name> with monoamine oxidase inhibitors (“MAOIs”) (see section ‘Do not take <Invented name>’).

<Invented name> is not recommended to be taken with the following:

- carbamazepine (a medicine 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 also take:

- triptans (for migraine) or selective serotonin re-uptake inhibitors, “SSRIs” (for depression). If you experience confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles or diarrhoea you should call your doctor.
- 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. You may feel drowsy or feel faint. If this happens, tell your doctor.
- medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk having a fit may increase if you take <Invented name> at the same time. Your doctor will tell you whether <Invented name> is suitable for you.
- certain antidepressants. <Invented name> 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.

- 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 <Invented name> may be altered if you also take:

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

Your doctor will tell you which medicines are safe to take with <Invented name>.

<Invented name> with food, drink and alcohol

<Invented name> may make you feel drowsy. Alcohol may make you feel more drowsy, so it is best not to drink alcohol while you are taking <Invented name>.

Pregnancy and breast-feeding

As <Invented name> contains tramadol, you should not take this medicine during pregnancy or breast feeding. If you become pregnant during treatment with <Invented name> please consult your doctor before taking any further tablets.

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

Based on human experience tramadol is suggested not to influence female or male fertility. No data on the influence of the combination of tramadol and paracetamol on fertility are available.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

<Invented name> may make you feel drowsy and this may affect your ability to drive, or use tools and machines, safely.

3. How to take <Invented name>

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

You should take <Invented name> for as short a time as possible.

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

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.

The recommended starting dose, unless otherwise prescribed by your doctor, is 2 tablets for adults and adolescents over 12 years.

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 <Invented name> film-coated tablets per day.

Do not take <Invented name> more often than your doctor has told you.

Older People

In elderly 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 <Invented name>. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

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 <Invented name> 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.

How the product is to be accessed

1. Separate one <Invented name> tablet blister by tearing at the pre-cut lines.



Figure A

2. Peel the paper backing that covers one <Invented name> tablet on the blister card.

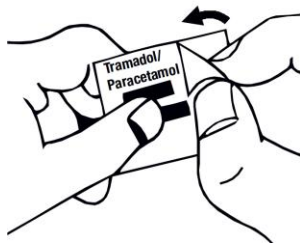


Figure B

3. Push the <Invented name> tablets through the foil.

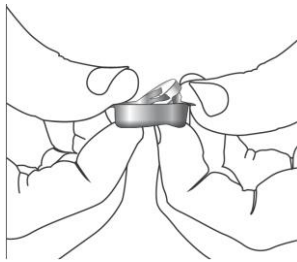


Figure C

If you take more <Invented name> 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 <Invented name>

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

If you stop taking <Invented name>

Generally, there will be no after-effects when treatment with <Invented name> 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 <Invented name> 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 (hyperhidrosis)
- headache, shaking
- confusional state, sleep disorders, mood changes (anxiety, nervousness, 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 ears, 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.

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

- fits, difficulties in carrying out coordinated movements
- addiction, delirium
- blurred vision, constriction of the pupil (miosis)
- speech disorders
- excessive dilation of the pupils (mydriasis)
- transient loss of consciousness (syncope).

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

- decrease in blood sugar level

The following are recognized 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 <Invented name> 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.

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 <Invented name> 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 <Invented name> 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.

Very rare cases of serious skin reactions have been reported.

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 <To be

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

5. How to store <Invented name>

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 and the edge of the blister after [EXP:]. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice your tablets appear to be discoloured or show any other signs of deterioration.

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

6. Contents of the pack and other information

What <Invented name> 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: Silica Colloidal Anhydrous (E551), Cellulose Microcrystalline (E460), Starch Pregelatinised (Maize Starch), Sodium Starch Glycolate Type-A, Stearic Acid (E570), Povidone K-30 (E1201) and Crospovidone (E1202).

Film-Coating: Hypromellose (E464), Titanium Dioxide (E171), Macrogol 400, Iron Oxide Yellow (E172), Polysorbate (E433) and Carnauba Wax (E903).

What <Invented name> looks like and contents of the pack

Light yellow, film coated, Capsule shaped tablets about 15.98 X 7.14 mm, engraved "AN506" on one side and plain on other side.

<Invented name> is available in perforated unit dose blister packs containing 10x1, 20x1, 30x1, 60x1 and 90x1 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

<[To be completed nationally]>

Manufacturer:

<[To be completed nationally]>

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

< {Name of the Member State} > < {Name of the medicinal product} >

This leaflet was last revised in {MM/YYYY}.

<[To be completed nationally]>