

Tramacet® 37.5mg/325mg Film-coated Tablets/Zaldiar® 37.5mg/325mg Film-coated Tablets

(Tramadol hydrochloride/Paracetamol)

Package Leaflet: Information for the User

Your medicine is known by one of the above names but will be referred to as Tramacet throughout this leaflet.

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, please 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 Tramacet is and what it is used for
- 2) What you need to know before you take Tramacet
- 3) How to take Tramacet
- 4) Possible side effects
- 5) How to store Tramacet
- 6) Contents of the pack and other information

1) What Tramacet is and what it is used for

Tramacet 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 Tramacet

Do not take Tramacet

- if you are allergic to tramadol hydrochloride, 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 Tramacet. 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 before taking Tramacet

- if you take other medicines containing paracetamol or tramadol
- if you have liver problems or disease as your eyes and skin may turn yellow, which may suggest jaundice
- 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 (being sick)
- if you are dependent on any medicine (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 Tramacet).

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

Other medicines and Tramacet

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

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

Do not take Tramacet with MAOIs (see section 'Do not take Tramacet').

Tramacet is not recommended to be taken with the following:

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

The risk of side effects increases:

- if you are taking triptans (used for migraine) or selective serotonin re-uptake inhibitors (SSRIs, used for depression). Check with your doctor if you experience confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles or diarrhoea.
- if you are taking 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, or medicines to treat allergies. Check with your doctor if you feel drowsy or feel faint.

- 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 Tramacet at the same time. Your doctor will tell you whether Tramacet is suitable for you.
- if you are taking certain antidepressants. Tramacet 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.
- if you are taking warfarin or phenprocoumon (for blood thinning). The effectiveness of such medicines may be altered and bleeding may occur (see section 4).

The effectiveness of Tramacet may be altered if you also take:

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

Tramacet with food and alcohol

Do not drink alcohol while you are taking Tramacet, as you may feel drowsier.

Pregnancy, breast-feeding and fertility

Do not take Tramacet while you are pregnant or breast-feeding.

Check with your doctor if you become pregnant during treatment with Tramacet and before taking any further tablets. Tramadol is excreted into breast milk. For this reason, you should not take Tramacet more than once during breast-feeding, or alternatively, if you take Tramacet 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

If you feel drowsy while taking Tramacet, do not drive, use tools 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:
 - 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.

Tramacet contains lactose

Lactose is an ingredient in these tablets.

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

3) How to take Tramacet

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

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.

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

Adults and adolescents over 12 years:

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 instructed by your doctor.

The shortest time between doses must be at least 6 hours.

Do not take more than 8 tablets per day.

Children under 12 years of age:

- not recommended.

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 Tramacet. 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.

Do not break or chew the tablets.

If you think that the effect of Tramacet 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 Tramacet 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 Tramacet

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 Tramacet

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

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 this medicine, please contact your doctor. Other side effect information is listed in section 4.

4) Possible side effects

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

Some side effects could be serious. Contact your doctor immediately if any of the following occur:

- 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 Tramacet with medicines used to thin the blood (e.g. warfarin, phenprocoumon).

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

Very common: may affect more than 1 in 10 people

- nausea
- dizziness, drowsiness.

Common: may affect up to 1 in 10 people

- vomiting (being sick), 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, uncoordinated movements
- addiction, delirium
- vision blurred, constriction of the pupil (miosis)
- speech disorders
- excessive dilation of the pupils (mydriasis)
- transient loss of consciousness (syncope)

Unknown: frequency unknown:

- 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:

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

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

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

5) How to store Tramacet

- Keep all medicines out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Do not use Tramacet after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.
- 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) Contents of the pack and other information**What Tramacet contains**

The active substances are tramadol hydrochloride and paracetamol.

Each tablet contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol.

The other ingredients are:

- **Tablet core:** powdered cellulose, pregelatinised starch (potato, maize and rice), sodium starch glycolate (type A), maize starch, magnesium stearate.
- **Film-coating:** hypromellose, lactose monohydrate, titanium dioxide (E 171), propylene glycol, talc, macrogol 6000 and yellow iron oxide (E172).

What Tramacet looks like and contents of the pack

Tramacet tablets are pale yellow film-coated tablets, marked with the manufacturer's logo on one side and marked T5 on the other side.

Tramacet tablets are packed in blister strips.

Tramacet tablets come in packs of 20 and 60 tablets.

PL 10383/2086 Tramacet® 37.5mg/325mg Film-coated
 Tablets/Zaldiar® 37.5mg/325mg Film-
 coated Tablets

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**Who makes and repackages your medicine?**

Your medicine is manufactured by Grunenthal GmbH, Zieglerstrasse 6, D-52078, Aachen, Germany. Procured from within the EU and repackaged by the Product Licence Holder: Primecrown Ltd., 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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