

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

TRAMACET® TABLETS

37,5 mg tramadol hydrochloride and 325 mg paracetamol

Read all of this leaflet carefully before you start taking TRAMACET

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- TRAMACET has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT TRAMACET CONTAINS

- The active ingredients are tramadol hydrochloride and paracetamol.
- The other ingredients are: carnauba wax, magnesium stearate, OPADRY® Light yellow, powdered cellulose, pregelatinised starch, purified water, sodium starch glycolate and starch (corn maize).

WHAT TRAMACET IS USED FOR

Tramadol, the active substance in **TRAMACET**, is a painkiller belonging to the class of the opioids that acts on the central nervous system. It is used for the management of moderate to moderately severe pain.

Paracetamol, the other active substance, has centrally acting analgesic effects.

BEFORE YOU TAKE TRAMACET

Do not take TRAMACET:

- if you are allergic to tramadol or paracetamol or any of the other ingredients of TRAMACET. (Refer to WHAT TRAMACET CONTAINS, above.);
- in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions);
- if you are taking MAO inhibitors (certain medicines used for depression) or have taken them in the last 14 days before treatment with TRAMACET.

Take special care with TRAMACET:

- if you think that you are addicted to other pain relievers (opioids);
- if you suffer from consciousness disorders (if you feel that you are going to faint);
- if you are in a state of shock (cold sweat may be a sign of it);
- if you suffer from increased pressure in the brain (possibly after a head injury or brain disease);
- if you have difficulty in breathing;
- if you have a tendency towards epilepsy or fits;
- if you suffer from a liver or kidney disease;
- Tramadol works by being converted (metabolised) into its active component. If you convert (metabolise) Tramadol to this active component more rapidly and completely than other patients you are known as an ultra-rapid metaboliser. If you are an ultra rapid metaboliser you are more likely to have serious side effects, such as breathing difficulties, with slow or shallow breathing. If you experience these types of side effects, stop taking this medicine and consult with your doctor immediately.
- You may experience low levels of sodium in the blood (hyponatraemia) while taking this medicine. Symptoms of low blood sodium may include nausea and vomiting, headaches,

feeling confused, feeling very tired, feeling restless, feeling irritable, muscle weakness, spasms or cramps and seizures. Elderly patients and patients taking other medicines that lower sodium in the blood are most at risk for this side effect. If you get any of these symptoms while taking TRAMACET, consult with your doctor immediately

In such cases, please consult your doctor before taking the medicine.

In the event of overdose or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Serious skin reactions

Serious skin reactions such as generalised exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), have been reported very rarely in patients receiving paracetamol, an active ingredient in TRAMACET (see 'What TRAMACET contains'). Discontinue use of TRAMACET at the first appearance of a skin rash or any other sign of allergy.

Taking TRAMACET with food and drink

Do not drink alcohol during treatment with TRAMACET as the effects of TRAMACET and alcohol may intensify each other.

Pregnancy and breast-feeding

The safe use of TRAMACET has not been demonstrated in pregnant and breast-feeding women. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery

TRAMACET may affect your reactions. If you feel that your reactions are affected, do not drive a car or other vehicle and do not use electric tools or operate machinery.

Taking other medicines with TRAMACET

Always tell your healthcare professional if you are taking other medicine. (This includes complementary or traditional medicines)

The pain relieving effect of TRAMACET may be reduced and the length of time it acts may be short ended,

- if you take medicines which contain carbamazepine (for epileptic fits).

The risk of side effects increases :

- if you take medicines which also depress brain function together with TRAMACET.
- if medicines which provoke fits or reduce the seizure threshold (e.g. medicines for the treatment of certain psychological diseases) are taken at the same time.
- if you take serotonergic medicines (for the treatment of depression) together with TRAMACET
- if you take medicines which prevent abnormal blood clotting. The effect of these medicines on blood clotting may be affected and small areas of bleeding under the skin may appear.

Other possible interactions

- TRAMACET should not be taken together with MAO inhibitors (medicines for the treatment of depression). When MAO inhibitors were taken 14 days before the administration of another opioid (pethidine), life-threatening interactions affecting the central nervous system, breathing and circulation were observed.
- Concomitant use with diflunisal may elevate paracetamol plasma levels.

HOW TO TAKE TRAMACET

Do not share medicines prescribed for you with any other person. Always take TRAMACET exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

Adults and children over 16 years:

Take 1 or 2 tablets every 4 to 6 hours as needed for pain relief up to a maximum of 8 tablets per day. Take the tablets with a sufficient quantity of liquid (e.g. one glass of water)

Renal impairment:

For patient with creatinine clearance < 30 ml/min, the dosing interval of TRAMACET should be increased not to exceed 2 tablets every 12 hours.

If you take more TRAMACET than you should:

Tramadol symptoms

Pin-point or wide pupils, vomiting, fall in blood pressure, fast heart beat, feeling faint, reduced levels of consciousness up to coma (deep unconsciousness), epileptic fits and difficulty in breathing up to stoppage of breathing may occur.

Paracetamol symptoms

First 24 hours – pallor, nausea, vomiting anorexia and abdominal pain.

12 to 48 hours- liver damage may become apparent.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

POSSIBLE SIDE EFFECTS

TRAMACET can have side effects. Not all side effects reported for TRAMACET are included in this leaflet. Should your general health worsen or if you experience any untoward effects while

taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Frequent side effects

- Nausea
- Dizziness
- Headache
- Tremor
- Stomach pain
- Constipation
- Diarrhoea
- Indigestion
- Flatulence
- Dry mouth
- Vomiting
- Lack of appetite
- Anxiety
- Confusion
- Unrealistic feeling of wellbeing
- Sleeplessness
- Nervousness
- Lack of energy
- Fatigue
- Hot flushes
- Itchy rash
- Sweating
- High blood pressure
- Aggravated high blood pressure

- Low blood pressure
- Irregular heart beat
- Heart Palpitation: abnormality of heartbeat that ranges from often unnoticed skipped beats or accelerated heart rate to very noticeable changes accompanied by dizziness or difficulty breathing.
- Increased rate of heart beat
- Liver test abnormalities
- Loss of muscle co – ordination
- Convulsions
- Increased muscle tone
- Migraine
- Aggravated migraine
- Involuntary muscle contractions
- A sensation of tingling or pins and needles of the skin
- Reduced consciousness or sensibility
- A sensation of whirling, dizziness and loss of balance
- Difficulty in swallowing
- Blood in stools
- Swollen tongue
- Ringing or buzzing sound in the ears
- Weight decrease
- Amnesia
- A state in which one's thoughts and feelings seem unreal or not to belong to oneself
- Depression
- Drug abuse
- Emotional lability
- Hallucinations
- Impotence

- Bad dreams
- Abnormal thinking
- Anaemia (a decrease in number of red blood cells (RBCs) or less than the normal quantity of hemoglobin in the blood)
- Difficulty breathing
- The presence of excessive protein (mainly albumin) in the urine
- Urinary disorder
- Reduced urine production
- Urinary retention
- Abnormal vision
- Chest pain
- Shivering or stiffness
- Fainting
- Withdrawal syndrome

Less Frequent

- Confusional state
- Excessive contraction of the pupil of the eye
- Prolonged dilatation of the pupil of the eye
- Speech disorder
- Movement disorder
- Low blood sugar. (Most cases were in patients who had existing risk factors such as diabetes, kidney disease or in elderly patients)
- Low levels of sodium in the blood and/or inappropriate antidiuretic hormone secretion (SIADH)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF TRAMACET

Keep TRAMACET in a cool, dry place, at or below 25 °C.

Store all medicines out of reach of children.

Protect from light and moisture

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF TRAMACET

Blister packs of 2, 10, 20, 30, 60, 100 or 500 tablets.

IDENTIFICATION OF TRAMACET

Light yellow, film-coated capsule-shaped tablet engraved “J-C” on one side and “T/P” on the other.

REGISTRATION NUMBER

35/2.9/0010

NAME AND ADDRESS OF REGISTRATION HOLDER



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