Package leaflet: Information for the user
Tramapa 37.5 mg/325 mg tablets
Tramadol hydrochloride/Paracetamol

Read all of this leaflet carefully before starting to take 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Tramapa is and what it is used for

Tramapa is a combination of two analgesics, tramadol and paracetamol, which act together to relieve pain. Tramapa is indicated for the symptomatic treatment of moderate to intense pain, provided that your doctor thinks that the combination of tramadol and paracetamol is necessary.

Tramapa should only be used by adults and children over the age of 12.

2. What you need to know before you take Tramapa

Do not take Tramapa :
- If you are allergic to tramadol, paracetamol or any of the other ingredients of this medicine (listed in section 6).
- In case of acute alcohol poisoning or if you are taking medicines to sleep, strong painkillers or other psychotropic medicines (medicines that may alter mood and emotions).
- If you are taking MAO inhibitors (certain medicines used to treat depression or Parkinson's disease), or if you have taken them in the 14 days prior to treatment with Tramapa .
- If you suffer from severe liver disease.
- If you have epilepsy that is not adequately controlled with your current treatment.

Warnings and precautions:
- If you are taking other medicines that contain paracetamol or tramadol.
- If you have liver problems or liver disease or if you notice that your eyes or skin acquire a yellowish tone. This may be indicative of jaundice or problems with your bile ducts.
- If you have kidney problems.
- If you have severe respiratory difficulties, such as asthma or serious lung problems.
- If you have epilepsy or have suffered seizures.

- If you have recently suffered from head trauma or intense headaches associated with vomiting.
- If you are dependent on any other medicine used for pain relief, such as morphine.
- If you are taking other medicines for the treatment of pain that contain buprenorphine, nalbuphine or pentazocine.
- If you are going to receive anaesthesia. Tell your doctor or dentist that you are using Tramapa .

If any of these problems occur or have occurred in the past while taking Tramapa , please tell your doctor. He/she will decide whether you should continue taking this medicine.

Use of Tramapa with other medicines:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Important: this medicine contains paracetamol and tramadol. Tell your doctor if you are taking any other medicine that contains paracetamol or tramadol so that the maximum daily dose is not exceeded.

You should not take Tramapa together with monoamine oxidase inhibitors (MAOIs) (see section "Do not take Tramapa ").

The use of Tramapa is contraindicated if you are on treatment with:

- Carbamazepine (medicine normally used to treat epilepsy or some types of pain, such as attacks of intense pain in the face called trigeminal neuralgia).
- Buprenorphine, nalbuphine or pentazocine (opioid analgesics). Pain relief may be reduced.

The risk of adverse effects increases if you are also using:

- Triptans (to treat migraines) or selective serotonin reuptake inhibitors, "SSRIs" (for the treatment of depression). If you experience confusion, agitation, fever, sweating, uncoordinated movements of the extremities or eyes, uncontrollable muscle contractions or diarrhoea, you should call your doctor.
- Sedatives, sleeping pills, other analgesics such as morphine and codeine (also when used for treating a cough), baclofen (muscle relaxant), some medicines to decrease blood pressure and antidepressants or medicines for the treatment of allergies. You may feel tired or dizzy. If this occurs, consult your doctor.
- Antidepressants, anaesthetics, neuroleptics (medicines that affect your mood) or bupropion (medicine that is used to help you stop smoking). The risk of suffering from an attack may increase. Your doctor will tell you whether Tramapa is suitable for you.
- Warfarin or phenprocoumon (medicine used to prevent blood clots). The effectiveness of these medicines may be altered and there may be a risk of bleeding. You should tell your doctor immediately about any prolonged or unexpected bleeding.
- Medicines that facilitate or may cause seizures, such as the case of certain antidepressants or antipsychotics. The risk of seizures increases if you take Tramapa at the same time as these medicines. Your doctor will tell you whether Tramapa is suitable for you.
- Medicines for the treatment of depression. Tramapa may interact with these medicines and you may experience symptoms such as involuntary, rhythmic muscle contractions, including the muscles that control eye movement, agitation, excessive sweating, tremors, exaggerated reflexes, increased muscle tension and body temperature above 38ºC.

The effectiveness of Tramapa may be altered if you are also using:

- Metoclopramide, domperidone or ondansetron (medicines for the treatment of nausea and vomiting).
- Cholestyramine (medicine that reduces cholesterol in the blood).
- Ketoconazole and erythromycin (medicines used against infections).

Your doctor will know which medicines can safely be used together with Tramapa .

Taking Tramapa with food, drink and alcohol:

You should not drink alcoholic beverages if you are taking this medicine.

Pregnancy, breast-feeding and fertility:

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

As Tramapa contains tramadol, the use of this medicine is not recommended during pregnancy. If you become pregnant during treatment with Tramapa , consult your doctor before taking the next tablet.

Tramadol may pass into breast milk. For this reason, you should not take Tramapa more than once during breastfeeding or, alternatively, if you take Tramapa more than once, you should stop breastfeeding.

Driving and use of machinery:
Ask your doctor if you can drive or use machinery during treatment with this medicine. It is important that before driving or using machinery, you observe how this medicine affects you. Do not drive or use machinery if you feel sleepy or dizzy, have blurred vision or see double, or have difficulty concentrating. Take special care at the start of treatment, after a dose increase, after a change of formulation and/or when administering it together with other medicines.

3. How to take Tramapa

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

The dose should be adjusted to the intensity of the pain and your individual sensitivity. Normally the lowest possible pain-relieving dose should be taken.

You should take Tramapa for the shortest possible time.

Unless your doctor prescribes otherwise, the recommended starting dose for adults and adolescents over the age of 12 is 2 tablets.

If required, the dose can be increased, as recommended by your doctor. The shortest interval between doses should not be less than 6 hours.

Do not take more than 8 tablets of Tramapa per day.

Do not take Tramapa more often than your doctor has indicated.
Your doctor may increase the interval between doses:
- If you are over 75 years of age.
- If you have kidney problems.
- If you have liver problems.

Use in children and adolescents:
Use of this medicine is not recommended in children under the age of 12.

Elderly patients:
In elderly patients (over the age of 75), tramadol excretion may be slow. If this applies to you, your doctor may recommend prolonging the dosing intervals.

Patients with liver or kidney failure/patients on dialysis
If you suffer from severe liver or kidney disease, treatment with Tramapa is not recommended. If you suffer from moderate liver or kidney disorders, your doctor may prolong the dosing intervals.

<u>Method of administration:</u>

The tablets can be swallowed whole or split in half with a glass of liquid, preferably water. The tablet score line is used to break the tablet if it is difficult to swallow whole.

If you believe the action of Tramapa is too strong (i.e. you feel very drowsy or have difficulty breathing) or too weak (i.e. you do not have enough pain relief), tell your doctor.

If you take more Tramapa than you should:
You should talk to your doctor or pharmacist even if you feel well. There is a risk of damage to the liver that will only be evident later.
In the event of overdose or accidental intake, go to a hospital immediately or call the Toxicology Information Service indicating the medicine and the amount taken.

If you forget to take Tramapa :
If you forget to take the tablets, it is possible that your pain will return. Do not take a double dose to make up for forgotten doses; simply continue taking the tablets as usual.

If you stop taking Tramapa :
In general, there are no side effects after stopping treatment with Tramapa . However, on rare occasions, patients who have been taking Tramapa for a period of time and who stop their treatment suddenly may feel unwell (see section 4 "Possible side effects"). If you have been taking Tramapa for some time, you should consult your doctor before stopping the treatment, as your body may have become used to it. If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Tramapa can cause side effects, although not everybody gets them.

Very common: may affect more than 1 in every 10 patients:
- nausea
- dizziness or drowsiness

Common: may affect between 1 to 10 in 100 patients:
- vomiting, digestive problems (constipation, flatulence or diarrhoea), stomach pain or dry mouth
- itching or increased sweating
- headache or agitation
- confusion, sleep disorders or mood changes (anxiety, nervousness or euphoria – sensation of feeling "in a good mood" all the time)

Uncommon: may affect between 1 to 10 in 1,000 patients:
- tachycardia, hypertension or heart rate and rhythm disorders
- difficulty or pain upon urinating
- skin reactions (e.g. rash or hives)
- tingling sensation, numbness, or pins and needles in the extremities, noises in the ear or involuntary muscle spasms
- depression, nightmares, hallucinations, (hearing or seeing something that does not really exist) or memory loss
- difficulty swallowing or blood in faeces
- chills, hot flushes or chest pain
- difficulty breathing.

Rare: may affect between 1 to 10 in 10,000 patients:
- seizures or difficulty carrying out coordinated movements
- addiction

- blurred vision

Frequency not known (cannot be estimated from the available data):
- Decreased blood sugar level (hypoglycaemia)

The following known side effects have been reported by people who have taken medicines that contain only tramadol or only paracetamol. However, if you experience any of these symptoms while you are taking Tramapa , you should tell your doctor:

- Sensation of light-headedness when standing up after sitting or lying down, low heart rate, fainting, changes in appetite, muscle weakness, slower or weaker breathing, mood changes, activity changes, perception changes or aggravation of asthma.
- On rare occasions, skin rashes indicative of allergic reactions may develop with sudden swelling of the face and neck, shortness of breath or a drop in blood pressure and dizziness.

If this occurs, stop treatment and see your doctor immediately. You should not take this medicine again.

In rare cases, using a medicine such as tramadol may cause dependence, thus making it difficult to stop taking the medicine.
On rare occasions, people who have been taking tramadol for some time may feel unwell if treatment is stopped suddenly. They may feel agitated, anxious, nervous or shaky. They may be hyperactive, find it difficult to sleep or have digestive and intestinal disorders. Very few people may also have panic attacks, hallucinations, unusual perceptions such as itching, tingling sensation and numbness, and noises in the ear (tinnitus). If you experience any of these symptoms after stopping treatment with Tramapa , please consult your doctor.
In exceptional cases, blood tests may reveal certain abnormalities, such as low platelet count, which may give rise to bleeding gums or nosebleeds.
The use of Tramapa together with anticoagulants (e.g. phenprocoumon or warfarin) may increase the risk of bleeding. You should tell your doctor immediately about any prolonged or unexpected bleeding.

Serious skin reactions have been reported on very rare occasions.

If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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

5. How to store Tramapa

Keep this medicine out of the sight and reach of children.
This medicinal product does not require any special storage conditions.

Do not use Tramapa after the expiry date which is stated on the pack (after EXP). The expiry date refers to the last day of that month.
Do not use this medicine if you notice visible signs of deterioration.

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

6. Contents of the pack and other information

Composition of Tramapa :
The active ingredients are tramadol hydrochloride and paracetamol.
One tablet contains 37.5 mg of tramadol hydrochloride and 325 mg of paracetamol.

The other ingredients are: Povidone, magnesium stearate, anhydrous colloidal silica, sodium carboxymethyl potato starch (Type A) and pregelatinised maize starch.

Product Appearance and contents of the pack:
Tramapa is presented in the form of tablets for oral administration, in packs of 20 tablets.

Marketing Authorisation Holder:
Manufactured by:
Ferrer Internacional, S.A. Gran Vía Carlos III, 94.
08028 Barcelona (Spain/Espagne)

Manufacturing site:
Ferrer Internacional, S.A.
Joan Buscallà, 1-9
Sant Cugat del Vallès,Barcelona (Spain/Espagne)

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