Package leaflet: Information for the user

Tradol Plus 37.5 mg/325 mg 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 Tradol Plus is and what it is used for

Tradol Plus is a combination of two analgesics (pain killers), tramadol and paracetamol, which act together to relieve pain.

Tradol Plus is indicated for the treatment of moderate to severe pain when your doctor recommends that a combination of tramadol and paracetamol is needed.

Tradol Plus should only be taken by adults and adolescents 12 years and older.

2. What you need to know before you take Tradol Plus

Do not take Tradol Plus
- if you are allergic to tramadol, 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 taking medicines called monoamine oxidase (MAO) inhibitors (certain medicines used to treat depression or Parkinson's disease) or if you have taken them in the last 14 days before treatment with Tradol Plus
- if you have 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 Tradol Plus if you
- are taking other medicines containing paracetamol or tramadol
- have liver problems or liver disease or if you notice your eyes or skin turning yellow. This may suggest jaundice or bile duct problems.
- 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

- suffer from consciousness disorders of unknown origin (if you feel you are going faint)
- are dependent on any medicine including those used to relieve pain, for example morphine
- are taking other medicines for pain treatment containing buprenorphine, nalbuphine or pentazocine
- are going to have an anaesthetic. Tell your doctor or dentist that you are taking Tradol Plus.

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

Children
The use of Tradol Plus is not recommended for children under 12 years of age because its safety and efficacy have not been established in this age group.

Other medicines and Tradol Plus
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 also paracetamol or tramadol, so that you do not exceed the maximum daily doses.

You **must not take** Tradol Plus if you are taking monoamine oxidase (MAO) inhibitors (see section "Do not take Tradol Plus").

Tradol Plus is not recommended to be taken with the following medicines:
- carbamazepine, phenytoin or phenobarbital (medicines commonly used to treat epilepsy or certain types of pain)
- isoniazid or rifampicin (tuberculosis medicine)
- St John's wort (*Hypericum perforatum)*
- buprenorphine, nalbuphine or pentazocine (opioid type pain relievers). The pain relieving effect may be reduced.

The risk of side effects increases if you are also taking:
- 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.
- sedative medicines such as benzodiazepines or related medicines (tranquillizers, sleeping pills.) Concomitant use of Tradol Plus and sedative medicines such as benzodiazepines or related medicines 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 Tradol Plus 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.

- other pain relievers such as morphine or codeine (also used to treat cough), baclofen (a muscle relaxant), medicines used to lower blood pressure 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 of having a fit may increase if you take Tradol Plus at the same time. Your doctor will tell you whether Tradol Plus is suitable for you.
- certain antidepressants. Tradol Plus 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 (medicine used to prevent blood clots). The effectiveness of these medicines may be altered and bleeding may occur. Inform your doctor immediately about any prolonged or unexpected bleeding.
- chloramphenicol (medicine to treat infections) given via injection: Your doctor may check your chloramphenicol blood concentrations.

The effectiveness of Tradol Plus may be altered if you are also taking any of the following medicines:
- metoclopramide, domperidone or ondansetron (medicines used to treat nausea and vomiting).
- cholestyramine (medicine to reduce cholesterol in the blood). After taking Tradol Plus wait at least 1 hour before you take cholestyramine.
- probenecid (medicine used primarily to treat gout and hyperuricemia): Your doctor may reduce the dose of Tradol Plus.

Your doctor will tell you which medicines are safe for you when taking Tradol Plus.

Tradol Plus with alcohol
Tradol Plus may make you feel drowsy. Alcohol may make you feel drowsier, so it is best not to drink alcohol while you are taking Tradol Plus.

Pregnancy and 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.

Do not take Tradol Plus if you are pregnant. Inform your doctor if you become pregnant during treatment with Tradol Plus.

Tramadol is excreted into breast milk. For this reason, you should not take Tradol/Plus more than once during breast-feeding, or alternatively, if you take Tradol/Plus more than once, you should stop breast-feeding.

Driving and using machines
Tradol Plus may make you feel drowsy and this may affect your ability to drive or use tools and machines safely.

3. How to take Tradol Plus

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

Take Tradol Plus for the shortest period of time possible.

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.

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

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 Tradol Plus tablets a day.
Do not take Tradol Plus more frequently than advised by your doctor.

If you think that the effect of Tradol Plus 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.

Elderly patients
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 Tradol Plus. 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.

The score line is not intended for breaking the tablet.
Swallow the tablets whole with sufficient liquid. Do not divide, chew or crush the tablets.

If you take more Tradol Plus than you should
Contact a doctor immediately, even if you feel well, since there is a risk of severe liver damage which may only show later.

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

If you stop taking Tradol Plus
Generally, there will be no after-effects when treatment with Tradol Plus is stopped. However, rarely, it may happen that some patients feel unwell after a sudden stop in the treatment when they have been taking it for some time (see section 4 "Possible side effects"). If you have been taking Tradol Plus for some time, you should check with your doctor before stopping treatment since 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.

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, tongue or throat, 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 Tradol Plus 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, digestion problems (constipation, flatulence, diarrhoea), stomach pain, dry mouth
- itching, sweating
- headache, shaking
- confusion, sleep disorders, mood changes (anxiety, nervousness, euphoria – 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
- 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
- increase in liver enzymes (hepatic transaminases), loss of certain proteins with the urine (albuminuria).

Rare: may affect up to 1 in 1,000 people
- fits, movement coordination problems
- addiction, delirium
- blurred vision, constriction of the pupils (miosis), excessive dilation of the pupils (mydriasis)
- speech disorders
- transient loss of consciousness (syncope).

Frequency not known
- 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. However, if you experience any of these symptoms while taking Tradol Plus, you should inform 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 (generally decrease, occasionally increased), changes in perception
- worsening of existing asthma
- nose bleeds or bleeding gums, which may result from a low blood platelet count
- severe reduction in number of white blood cells which makes infections more likely with possible signs of fever and sore throat (agranulocytosis).

Rarely, using a medicine of the type of tramadol may make you become dependent on it, making it hard to stop taking it. In rare cases, people who have been taking tramadol for some time may feel unwell when suddenly stopping it. They may feel agitated, anxious, nervous or shaky. They may be hyperactive, have difficulty sleeping and 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 symptoms after stopping Tradol Plus, please consult your doctor.

Use of Tradol Plus 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Tradol Plus

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister and strips after EXP. The expiry date refers to the last day of that month.

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 Tradol Plus contains

- The active substances are tramadol hydrochloride and paracetamol.
  Each tablet contains 37.5 mg of tramadol hydrochloride and 325 mg of paracetamol.
- The other ingredients are povidone, magnesium stearate, colloidal anhydrous silica, sodium starch glycolate (Type A), pregelatinised maize starch.

What Tradol Plus looks like and contents of the pack
Tradol Plus are white scored tablet of oblong shape (15 x 6.5 mm) and are for oral administration. The score line is not intended for breaking the tablet.

The tablets are packed in aluminium/polyethylene strips or aluminium/PVC-PVDC blisters. The packages contain 2, 10, 20, 30, 40, 60 and 100 tablets.
(The pack size 100 is limited for hospital use.)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Ferrer Internacional, S.A., Joan Buscallà, 1-9, Sant Cugat del Vallès (Barcelona), Spain.
Salutas Pharma GmbH, Otto-von-Guericke Allee 1, D-39179 Barleben, Germany.

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

Belgium	Tramadol/Paracetamol Sandoz 37,5 mg/325 mg tabletten
	Tramadol/Paracetamol Sandoz 75 mg/650 mg tabletten
Croatia	Tramadolor DUO 37,5 mg/325 mg tablete
	Tramadolor DUO 75 mg/650 mg tablete
Czech Republic	Tramadol/Paracetamol Sandoz 37,5 mg/325 mg
	Tramadol/Paracetamol Sandoz 75 mg/650 mg
Denmark	Tramadol/Paracetamol Sandoz
France	Tramadol/Paracetamol PTR
Germany	Tramadolor plus Paracetamol 37,5 mg/325 mg Tabletten
	Tramadolor plus Paracetamol 75 mg/650 mg Tabletten
Hungary	Tramadolor Plus 37,5 mg/325 mg tabletta
	Tramadolor Plus 75 mg/650 mg tabletta
Ireland	Tradol Plus 37.5 mg/325 mg Tablets
Italy	Tramadolo e paracetamolo Sandoz
Luxembourg	Tramadol/Paracetamol Sandoz 37,5 mg/325 mg comprimés
	Tramadol/Paracetamol Sandoz 75 mg/650 mg comprimés

The Netherlands	Tramadol HCl/Paracetamol Sandoz 37,5/325 mg, tabletten
	Tramadol HCl/Paracetamol Sandoz 75/650 mg, tabletten
Norway	Tramadol/Paracetamol Sandoz
Poland	Tramadol+Paracetamol Sandoz
	Delparan MAX
Portugal	Tramadol + Paracetamol Litexil
Romania	Tramadol/Paracetamol Sandoz 37,5 mg/325 mg comprimate
	Tramadol/Paracetamol Sandoz 75 mg/650 mg comprimate
Slovenia	TADOCET 37,5mg/325 mg tablete
	TADOCET 75 mg/650 mg tablete
Slovakia	DELPARAN 37,5 mg/325 mg tablety
	DELPARAN 75 mg/650 mg tablet
Sweden	Trampara®

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