CONTAINS PARACETAMOL

PACKAGE LEAFLET: INFORMATION FOR THE USER
Tramadol/Paracetamol Rowa 37.5 mg/325 mg 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 of the side effects talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Tramadol/Paracetamol Rowa is and what it is used for
Tramadol/Paracetamol Rowa is a combination of two analgesics, tramadol and paracetamol, which act together to relieve your pain.
Tramadol/Paracetamol Rowa is intended for use in the treatment of moderate to severe pain when your doctor recommends that a combination of tramadol and paracetamol is needed.

Tramadol/Paracetamol Rowa should only be taken by adults and adolescents over 12 years.

2. What you need to know before you take Tramadol/Paracetamol Rowa
Do not take Tramadol/Paracetamol Rowa
- 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 Tramadol/Paracetamol Rowa
- if you suffer from a severe liver disorder
- if you have epilepsy that is not adequately controlled on your current medicine.

Warnings and Precautions
Check with your pharmacist or doctor before taking Tramadol/Paracetamol Rowa 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
- suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Tramadol/Paracetamol Rowa). There is a small risk that you may experience a so-called serotonin syndrome that can occur after having taken tramadol in combination with certain antidepressants or tramadol alone. Seek medical advice immediately if you have any of the symptoms related to this serious syndrome (see section 4 'Possible side effects').

- are going to have an anaesthetic. Tell your doctor or dentist that you are taking Tramadol/Paracetamol Rowa.

During treatment with Tramadol/Paracetamol Rowa, tell your doctor straight away if:
If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Tolerance, dependence, and addiction
This medicine contains tramadol which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Tramadol/Paracetamol Rowa can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Tramadol/Paracetamol Rowa if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Tramadol/Paracetamol Rowa it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Tramadol/Paracetamol Rowa).

Sleep-related breathing disorders
Tramadol/Paracetamol Rowa can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Tramadol/Paracetamol Rowa:
Extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels). If you have these symptoms, contact your doctor, who will decide if you need to take hormone supplement.

If any of the above apply to you (or if you are not sure), talk to your doctor or pharmacist before taking this medicine.

Tramadol is transformed in the liver by an enzyme. Some people have a variation of this enzyme and this can affect people in different ways. In some people, they may not get enough pain relief, but other people are more likely to get serious side effects. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Children and adolescents.
Use in children with breathing problems:
Tramadol is not recommended in children with breathing problems, since the symptoms of tramadol toxicity may be worse in these children.

Other medicines and Tramadol/Paracetamol Rowa
Tell your doctor or pharmacist if you are taking or 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.

Please inform your doctor or pharmacist if you are taking:

- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section2).

You **must not** take Tramadol/Paracetamol Rowa together with monoamine oxidase inhibitors ("MAOIs") (see section 2 "Do not take Tramadol/Paracetamol Rowa").
Tramadol/Paracetamol Rowa is not recommended to be taken with the following:
- carbamazepine (a medicine commonly 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.
- gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).

The risk of side effects increases, if you are taking
- medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk of having a fit may increase if you take Tramadol/Paracetamol Rowa at the same time. Your doctor will tell you whether Tramadol/ Paracetamol Rowa is suitable for you.
- certain antidepressants, Tramadol/Paracetamol Rowa may interact with these medicines and you may experience serotonin syndrome ((see section 4 'Possible side effects')
- triptans (for migraine) or selective serotonin reuptake 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.
- tranquillizers, 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.
- antidepressants, anaesthetics, neuroleptics (medicines that affect the state of mind) or bupropion (to help stop smoking)
- 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 Tramadol/Paracetamol Rowa may be altered if you also take
- metoclopramide, domperidone or ondansetron (medicines for treatment of nausea and vomiting)
- cholestyramine (medicine to reduce cholesterol in the blood)
- ketoconazole or erythromycin (medicines against infections).

Concomitant use of Tramadol/Paracetamol Rowa and sedative medicines such as benzodiazepines or related drugs 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 Tramadol/Paracetamol Rowa 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.
Your doctor will tell you which medicines are safe to take with Tramadol/Paracetamol Rowa.

Taking Tramadol/Paracetamol Rowa with food and drink and alcohol
Tramadol/Paracetamol Rowa may make you feel drowsy. Alcohol may make you feel drowsier, so it is best not to drink alcohol while you are taking Tramadol/Paracetamol Rowa.

Pregnancy breast-feeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy:
As Tramadol/Paracetamol Rowa contains tramadol, you should not take this medicine during pregnancy.
If you become pregnant during treatment with Tramadol/Paracetamol Rowa, please consult your doctor before taking any further tablets.

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

Driving and using machines
Tramadol/Paracetamol Rowa may make you feel drowsy and this may affect your ability to drive, or use tools and machines, safely. If affected, do not drive or operate machinery.

Tramadol/Paracetamol Rowa contains sodium.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Tramadol/Paracetamol Rowa
Always take this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Tramadol/Paracetamol Rowa when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also section 2).

You should take Tramadol/Paracetamol Rowa for as short a time as 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.

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 Tramadol/Paracetamol Rowa. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

Recommended dose:

Adults:
Unless otherwise prescribed by your doctor, the usual starting dose for adults and adolescents over 12 years is 2 tablets.
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 Tramadol/Paracetamol Rowa film-coated tablets per day.

Do not take Tramadol/Paracetamol Rowa more often than your doctor has told you.
Your doctor may increase the time between doses
- if you are older than 75 years
- if you have kidney problems
- if you have liver problems.

Method of administration:
The tablets are for oral use.
Swallow the tablets whole with sufficient liquid.
If you think that the effect of Tramadol/Paracetamol Rowa 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.

Children and adolescents:
The use in children below the age of 12 years is not recommended

If you take more Tramadol/Paracetamol Rowa than you should:
•If you take more Tramadol/Paracetamol Rowa than you should, talk to your doctor or go to a hospital straight away even if you feel well. Immediate medical advice should be sought in an event of overdosage, because of the risk of irreversible liver damage.
The irreversible liver damage may only show later.
•Take the medicine pack with you so that the doctor knows what you have taken.

If you forget to take Tramadol/Paracetamol Rowa:
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 Tramadol/Paracetamol Rowa:

You should not suddenly stop taking this medicine unless your doctor tells you to. If you want to stop taking your medicine, discuss this with your doctor first, particularly if you have been taking it for a long time. Your doctor will advise you when and how to stop, which may be by lowering the dose gradually to reduce the chance of developing unnecessary side effects (withdrawal symptoms).

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 less than 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, a feeling of high spirits).

Uncommon: (may affect less than 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 ear, 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 less than 1 in 1000 people):
- fits, difficulties in carrying out coordinated movements
- addiction
- blurred vision, constriction of the pupil (miosis)
- excessive dilation of the pupils (mydriasis)
- speech disorders
- transient loss of consciousness (syncope)
- delirium.

Very rare: (may affect less than 1 in 10,000 people):
-cases of serious skin reactions have been reported.

Not known: (frequency cannot be estimated from the available data):
- decrease in blood sugar level
- hiccups
- serotonin syndrome, that can manifest as mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as fever, increase in heart rate, unstable blood pressure, involuntary twitching, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea) (see section 2 'What you need to know before you take Tramadol/Paracetamol Rowa).

-a serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

The following are recognised 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 Tramadol/Paracetamol Rowa 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.
• Using a medicine of the type of tramadol may make you become dependent on it, making it hard to stop taking it.
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 Tramadol/Paracetamol Rowa, 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 Tramadol/Paracetamol Rowa 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.

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 Tramadol/Paracetamol Rowa

Keep out of the sight and reach of children.
Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

Do not use the Tramadol/Paracetamol Rowa after the expiry date which is printed on the carton and the edge of the blister after [EXP]. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Tramadol/Paracetamol Rowa contains:
- The active substances are tramadol hydrochloride and paracetamol.

One film-coated tablet contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol.

- The other ingredients are:
Tablet core: Pregelatinised maize (corn) starch, stearic acid, povidone K, croscarmellose sodium
Film-coating: Opadry light yellow containing: hypromellose, titanium dioxide (E 171), polyethylene glycol, yellow iron oxide (E 172), polysorbate 80.

What Tramadol/Paracetamol Rowa looks like and contents of the pack
Tramadol /Paracetamol Rowa film-coated tablets are yellowish, cylindrical, biconvex film-coated tablets with 11 mm diameter.
Tramadol/Paracetamol Rowa film-coated tablets are packed in blister strips and comes in cartons of 20, 60 and 100 tablets.

Not all pack sizes will be marketed.

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