PACKAGE LEAFLET: INFORMATION FOR THE USER

CONTAINS PARACETAMOL

TRAMADOL HYDROCHLORIDE/PARACETAMOL 37.5mg/325mg
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 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. See section 4.

WHAT IS IN THIS LEAFLET

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1. WHAT TRAMADOL HYDROCHLORIDE/PARACETAMOL TABLETS ARE AND WHAT THEY ARE USED FOR

Tramadol Hydrochloride/Paracetamol tablets are used to treat moderate to severe pain when you doctor recommends that a combination of paracetamol and tramadol hydrochloride is needed.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRAMADOL HYDROCHLORIDE/PARACETAMOL TABLETS

Do not take Tramadol Hydrochloride/Paracetamol film coated tablets:

- if you are hypersensitive or have had an allergic reaction (for instance skin rash, swelling of the face, wheezing or difficulty breathing) to tramadol, paracetamol or any of the other ingredients (see section 6) in Tramadol Hydrochloride/Paracetamol tablets.
- 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 Tramadol Hydrochloride/ Paracetamol tablets. 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

Sleep-related breathing disorders

Tramadol hydrochloride/Paracetamol tablets 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.

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 Hydrochloride/Paracetamol 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 Hydrochloride/Paracetamol 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 Hydrochloride/Paracetamol, 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 Hydrochloride/Paracetamol).

Before you take Tramadol hydrochloride/Paracetamol tablets, check with your doctor or pharmacist if you:

- take other medicines containing paracetamol or tramadol.
- have liver problems or disease as your eyes and skin may turn yellow, which may suggest jaundice.
- 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 (being sick).
- are dependent on any medicine (for example morphine).
- take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine
- are going to have an anaesthetic (tell your doctor or dentist that you are taking Tramadol Hydrochloride/Paracetamol tablets).

- have 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.
- Suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Tramadol hydrochloride/ Paracetamol tablets').

During treatment with Tramadol Hydrochloride/Paracetamol tablets, 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).

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').

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.

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

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.

Talk to your doctor if you experience any of the following symptoms while taking Tramadol hydrochloride/Paracetamol: 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.

Other medicines and Tramadol hydrochloride/Paracetamol tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Please inform your doctor or pharmacist if you are taking:
- flucloxacillin (antiobitic), due to a serious risk of blood and fluid abnormality (called

metabolic acidosis) that must have urgent treatment (see section 2).

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.

You must not take Tramadol Hydrochloride/Paracetamol tablets together with monoamine oxidase inhibitors ("MAOIs") (see section 'Do not take Tramadol Hydrochloride/Paracetamol tablets').

Tramadol Hydrochloride/Paracetamol tablets are not recommended 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 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.
- if you are taking 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. You may feel drowsy or feel faint. If this happens, tell your doctor.
- concomitant use of Tramadol Hydrochloride/Paracetamol tablets 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 prescribes Tramadol Hydrochloride/Paracetamol tablets 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.
- 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 Hydrochloride/Paracetamol tablets at the same time. Your doctor will tell you whether Tramadol Hydrochloride/Paracetamol tablets are suitable for you.
- if you are taking certain antidepressants. Tramadol Hydrochloride/Paracetamol tablets may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects').
- if you are taking 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.
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics).
- medicines to treat psychiatric disorders (antipsychotics or neuroleptics).

- muscle relaxants.
- medicines to treat Parkinson's disease

The effectiveness of Tramadol Hydrochloride/Paracetamol tablets may be altered if you also take:

- metoclopramide, domperidone or ondansetron (medicines for treatment of nausea and vomiting).
- cholestyramine (medicine used to reduce cholesterol in the blood).

Your doctor will tell you which medicines are safe to take with Tramadol Hydrochloride/Paracetamol tablets.

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

Pregnancy and breast-feeding
Do not take Tramadol Hydrochloride/Paracetamol tablets while you are pregnant.
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.

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

Driving and using machines
If you feel drowsy while taking Tramadol Hydrochloride/Paracetamol tablets, do not drive, use tools or use machinery. The medicine is likely to 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.

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

3. HOW TO TAKE TRAMADOL HYDROCHLORIDE/ PARACETAMOL TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse 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 Hydrochloride/Paracetamol tablets, 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 Hydrochloride/Paracetamol tablets for as short a time as possible.
The use in children below the age of 12 years is not recommended

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.

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 recommended by your doctor. The shortest time between doses must be at least 6 hours
Do not take more than 8 Tramadol Hydrochloride/Paracetamol tablets per day.
Do not take Tramadol Hydrochloride/Paracetamol tablets more often than your doctor has told you.

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 Tramadol Hydrochloride/Paracetamol tablets. 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.
They should not be broken or chewed.

If you think that the effect of Tramadol Hydrochloride/Paracetamol tablets 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.

If you take more Tramadol hydrochloride/Paracetamol tablets than you should

In such cases please contact your doctor or pharmacist immediately even if you feel well. After taking very high doses, pin-point pupils, vomiting, fall in blood pressure, fast heart beat, collapse, disturbed consciousness up to coma (deep unconsciousness), epileptic fits, and difficulty in breathing up to cessation of breathing and death may occur. In such cases a doctor should be called immediately.

An overdose of paracetamol can cause nausea and vomiting. There is a risk of liver damage which may only show later. Severe cases may lead to liver failure, brain issues, coma, or death.

If you forget to take Tramadol hydrochloride/Paracetamol tablets
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 hydrochloride/Paracetamol tablets
Generally, there will be no after-effects when treatment with Tramadol Hydrochloride/ Paracetamol tablets is stopped.
However, on rare occasions, people who have been taking tramadol for some time may feel unwell if they stop treatment abruptly (see section 4. "Possible Side Effects"). If you have been taking Tramadol Hydrochloride/Paracetamol tablets for some time, you should talk to your doctor if you want to stop because 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.

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 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 Tramadol Hydrochloride/ Paracetamol tablets 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 side effects (affecting more than 1 in 10 people treated)
- nausea.
- dizziness, drowsiness.

Common side effects (affecting less than 1 in 10, but more than 1 in 100 people treated)
- vomiting (being sick), digestion problems (constipation, flatulence, diarrhoea), stomach pain, dry mouth.
- itching, sweating.
- headache, shaking.
- confusion, sleep disorders, mood changes (anxiety, nervousness, feeling of high spirits).

Uncommon side effects (affecting less than 1 in 100, but more than 1 in 1,000 people treated)
- 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.
- increased liver enzymes
- Chills
- presence of albumin in urine, difficulties or pain on passing urine

Rare side effects (affecting less than 1 in 1,000, but more than 1 in 10,000 people treated)

- fits, uncoordinated movements.
- drug dependence
- blurred vision, pupil constriction or dilation
- transient loss of consciousness (syncope).
- delirium
- speech disorders
- excessive dilation of the pupils

Not known: frequency cannot be estimated from the available data:

- decrease in blood sugar level
- 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 Hydrochloride/Paracetamol Tablets, 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.
- Paracetamol intake alone or when taken together with the antibiotic flucloxacillin may induce a blood and fluid abnormality (high anion gap metabolic acidosis) when there is an increase in blood plasma acidity.
- Use of Tramadol Hydrochloride/Paracetamol Tablets 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.
- 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.

In rare cases, using a medicine of the type of tramadol may make you become dependent on it, making it hard to stop taking it. On rare occasions, 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 Hydrochloride/Paracetamol Tablets, please consult your doctor.

- Frequency not known: 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 Hydrochloride/Paracetamol Tablets").
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.
Very rare cases of serious skin reactions have been reported with paracetamol.
Rare cases of respiratory depression have been reported with tramadol.

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 HYDROCHLORIDE/ PARACETAMOL TABLETS

KEEP THIS MEDICINE 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 this medicine after the expiry date which is stated on the carton and blister. 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 waste water 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 hydrochloride/ Paracetamol film-coated tablets contain
The active substances are tramadol hydrochloride and paracetamol.
One (1) tablet contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol. The other ingredients are: Pregelatinised starch, Sodium starch glycolate (Type A), Cellulose Microcrystalline , Magnesium Stearate, Hypromellose, Titanium dioxide, Macrogol 400, Yellow Iron oxide, Polysorbate 80

What Tramadol hydrochloride/Paracetamol tablets look like and contents of the pack
Tramadol Hydrochloride/Paracetamol tablets are pale yellow, film-coated tablets, marked with "325" on one side and '37.5' on the other side.
Tramadol Hydrochloride/Paracetamol tablets are packed in blister strips. Tramadol Hydrochloride/ Paracetamol tablets comes in cartons of 60 Tablets

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