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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

WHAT IS IN THIS LEAFLET

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.

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').

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').

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.

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.

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.

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.

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 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 until you know how the medicine affects you

It may be an offence to drive while under the influence of this medicine.

There is further information for patients who are intending to drive in Great Britain – go to https://www.gov.uk/drug-driving-law

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 or pharmacist if you are not sure.

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. There is a risk of liver damage which may only show later.

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.

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4. POSSIBLE SIDE EFFECTS

Like all medicines, Tramadol Hydrochloride/Paracetamol tablets can cause side effects, however 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.
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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

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

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

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 hydrochloride/Paracetamol tablets').

In addition, the following side effects have been reported by people using medicines that contain only tramadol or only paracetamol:

- 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.
- nose bleeds or bleeding gums, which may result from a low blood platelet count
- serious skin reactions

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. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie

5. HOW TO STORE TRAMADOL HYDROCHLORIDE/ PARACETAMOL TABLETS

Keep this medicine out of the sight and reach of children

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

MARKETING AUTHORISATION HOLDER:
Athlone Pharmaceuticals Limited, Ballymurray, Co Roscommon, Ireland

MANUFACTURER:
Kent Pharmaceuticals Limited,

- Unit 200, Westminster 42, Westminster Industrial Estate, Repton Road, Measham, Swadlincote, DE 12 7DT, U.K.
- Joshna House, Crowbridge Road, Orbital Park, Ashford, Kent, TN24 0GR, U.K.

This medicinal product is authorised in the Member States of the EEA under the following names:
UK: Tramadol Hydrochloride/Paracetamol 37.5mg/325mg Film-Coated Tablets
Ireland: Tramadol Hydrochloride/Paracetamol 37.5mg/325mg Film-Coated Tablets

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