

## Package leaflet: Information for the user

### Tramadol hydrochloride and 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 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 Tramadol hydrochloride and Paracetamol is and what it is used for
2. What you need to know before you take Tramadol hydrochloride and Paracetamol
3. How to take Tramadol hydrochloride and Paracetamol
4. Possible side effects
5. How to store Tramadol hydrochloride and Paracetamol
6. Contents of the pack and other information

#### 1. What Tramadol hydrochloride and Paracetamol is and what it is used for

Tramadol hydrochloride and Paracetamol is used to treat moderate to severe pain when your doctor recommends that a combination of tramadol and paracetamol is needed.

#### 2. What you need to know before you take Tramadol hydrochloride and Paracetamol

##### Do not take Tramadol hydrochloride and Paracetamol:

- if you are allergic to tramadol hydrochloride, paracetamol or any of the other ingredients of this medicine (listed in section 6)
- 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 And Paracetamol. 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 on your current medicine.

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Tramadol hydrochloride and Paracetamol

- if you take other medicines containing paracetamol or tramadol
- if you have liver problems or disease as your eyes and skin turning yellow, which suggest jaundice
- if you have kidney problems
  - if you have severe difficulties in breathing, for example asthma or severe lung problems
  - if you have epilepsy or have already experienced fits or seizures
  - if you have recently suffered from a head injury, shock or severe headaches associated with vomiting (being sick)
  - if you are dependent on any medicines for example morphine)
- if you take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine
- if you are going to have an anaesthetic (tell your doctor or dentist that you are taking Tramadol hydrochloride and Paracetamol).
- if you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Tramadol hydrochloride and Paracetamol').

##### 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 And 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.

##### Sleep-related breathing disorders

Tramadol hydrochloride and Paracetamol contains an active substance that belongs to the group of opioids. Opioids can cause sleep-related breathing disorders, for example central sleep apnea (shallow/pause of breathing during sleep) and sleep-related hypoxemia (low level of oxygen in the blood).

The risk of experiencing central sleep apnea is dependent on the dose of opioids. Your doctor may consider decreasing your total opioid dosage if you experience central sleep apnea.

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 an enzyme of the 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 And

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 and Paracetamol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not exceed the maximum daily doses of paracetamol or tramadol from this or other medicines.

Do not take Tramadol Hydrochloride And Paracetamol with MAOIs (see section 'Do not take Tramadol Hydrochloride And Paracetamol').

Tramadol Hydrochloride And Paracetamol is not recommended to be taken with the following:

- carbamazepine (a medicine used to treat epilepsy or some types of pain)
- buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers).

Please inform your doctor or pharmacist if you are taking:

- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used, especially if you take the maximum daily dose of paracetamol for longer time. High anion gap metabolic acidosis is a serious disease that must have urgent treatment.

##### The risk of side effects increases

if you are taking triptans (used for migraine) or selective serotonin re-uptake inhibitors (SSRIs, used for depression). Check with your doctor if you experience confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles or diarrhoea.

- 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. Check with your doctor if you feel drowsy or feel faint.

Concomitant use of Tramadol Hydrochloride And Paracetamol 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 And Paracetamol 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 having a fit may increase if you take Tramadol Hydrochloride And Paracetamol at the same time. Your doctor will tell you whether Tramadol Hydrochloride And Paracetamol is suitable for you.
- if you are taking certain antidepressants. Tramadol Hydrochloride And Paracetamol 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 (see section 4).

##### The effectiveness of Tramadol hydrochloride and Paracetamol may be altered if you also take

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

##### Tramadol hydrochloride and Paracetamol with food and alcohol

Do not drink alcohol while you are taking Tramadol hydrochloride and Paracetamol, as you may feel drowsier.

##### Pregnancy, breast-feeding and fertility

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 Tramadol Hydrochloride And Paracetamol while you are pregnant or breast-feeding.

Check with your doctor if you become pregnant during treatment with Tramadol Hydrochloride And Paracetamol and before taking any further tablets.

##### Breast-feeding

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

Based on human experience tramadol is suggested not to influence female or male fertility. No data on the influence of the combination of tramadol and paracetamol on fertility are available.

Ask your doctor or pharmacist for advice before taking any medicine.

##### Driving and using machines

If you feel drowsy while taking Tramadol hydrochloride and Paracetamol, do not drive, use tools or use machinery. The medicine can 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 and Paracetamol 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 hydrochloride and Paracetamol

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

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.

Take Tramadol hydrochloride and Paracetamol for as short a time as possible and no longer than your doctor has told you.

#### Adults and adolescents over 12 years:

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 instructed by your doctor.

The shortest time between doses must be at least 6 hours.

Do not take more than 8 tablets per day.

#### Children under 12 years of age:

- not recommended.

#### 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 And Paracetamol. 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.

If you think that the effect of Tramadol hydrochloride and Paracetamol 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 and Paracetamol than you should

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

#### If you forget to take Tramadol hydrochloride and Paracetamol

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 and Paracetamol

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).

People may:

- feel agitated, anxious, nervous or shaky
- be over active
- have difficulty sleeping
- have stomach or bowel disorders.

Very few people may also get:

- panic attacks
- hallucinations, unusual perceptions such as itching, tingling and numbness
- ringing in the ears.

If you experience any of these complaints after stopping this medicine, please contact your doctor. Other side effect information is listed in section 4.

### 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 And Paracetamol 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 (being sick), digestion problems (constipation, flatulence, diarrhoea), stomach pain, dry mouth,
- itching, sweating (hyperhidrosis),
- headache, shaking
- confusional state, sleep disorders, mood changes (anxiety, nervousness, 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,
- 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, hallucination (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 enzyme values
- presence of albumin in urine, difficulties or pain on passing urine

#### Rare may affect up to 1 in 1,000 people;

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

#### Unknown: frequency unknown:decrease in blood sugar level (hypoglycaemia)

- 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 and Paracetamol').

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
- 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
- nose bleeds or bleeding gums, which may result from a low blood platelet count.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Tramadol hydrochloride and Paracetamol

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label, carton, and blister 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 Tramadol hydrochloride and Paracetamol contains

- The active substances are tramadol hydrochloride and paracetamol. Each film-coated tablet contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol.
- The other ingredients are  
*Tablet core:* Maize starch, powdered cellulose, sodium starch glycolate (Type A), starch, pregelatinized, Magnesium Stearate  
*Film-coating:* Hypromellose, titanium dioxide (E171), macrogol 400, iron oxide yellow (E172), polysorbate 80

#### What Tramadol hydrochloride and Paracetamol looks like and contents of the pack

Film-coated tablets

Light yellow, oblong shaped biconvex film coated tablets debossed with "1 03" on one side and plain on the other side.

Tramadol hydrochloride and Paracetamol film-coated tablets are available in white opaque PVC/PVdC – Aluminium foil blister pack or white opaque PVC/PVdC - Child resistant PVC backed Aluminium foil blister pack and white opaque HDPE container pack with polypropylene closure.

#### Pack sizes:

Blister pack: 10, 20, 30, 60, 90 & 100 film-coated tablets  
HDPE pack: 30, 250 & 1000 film-coated tablets

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

Milpharm Limited  
Ares Block, Odyssey Business Park  
West End Road  
Ruislip HA4 6QD  
United Kingdom

#### Manufacturer

APL Swift Services (Malta) Limited  
HF26, Hal Far Industrial Estate, Hal Far  
Birzebbugia, BBG 3000  
Malta

or

Milpharm Limited  
Ares Block, Odyssey Business Park  
West End Road  
Ruislip HA4 6QD  
United Kingdom

This leaflet was last revised in 07/2023.