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Package leaflet: Information for the user

This medicine contains tramadol hydrochloride which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

Tramadol Hydrochloride/Paracetamol 37.5 mg/325 mg film-coated tablets

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

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1. What Tramadol/ Paracetamol is and what it is used for

Tramadol/Paracetamol contains a combination of the active substances Tramadol hydrochloride/Paracetamol, which belongs to a group of medicines used to treat pain.

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

This medicine has been prescribed for you for tramadol/paracetamol. It contains the tramadol hydrochloride which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you take Tramadol/ Paracetamol

Do not take Tramadol/Paracetamol

- if you are allergic 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 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/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 by your current medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tramadol/Paracetamol Your doctor needs to know before you take Tramadol/Paracetamol if you have or have had any of the following conditions:

- taking other medicines containing Tramadol/Paracetamol
- 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/Paracetamol).
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Tramadol/Paracetamol to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea,

loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Adolescents and Adults a over 12 years

The recommended dosage is to start with 2 tablets, unless otherwise prescribed by your doctor. 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.

Your doctor may increase the time between doses if:

- you are older than 75 years
- you have kidney problems
- you have liver problems.

Children and adolescents

This medicine is not recommended in children and adolescents under 12 years of age.

Other medicines and Tramadol/Paracetamol

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. Your doctor will tell you which medicines are safe to take with Tramadol/Paracetamol.

Do not exceed the maximum daily doses of Tramadol/Paracetamol from this or other medicines.

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

Tramadol/Paracetamol is not recommended with the following medicines, as it may affect how well they work:

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

Tramadol/Paracetamol may increase the risk of side effects if you also take the following medicines:

- 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.
- tranquilizers, 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. Check with your doctor if you feel drowsy or feel faint.
- antidepressants, anaesthetics, medicines that affect the state of mind, or bupropion (used to help stop smoking). The risk of having a fit may increase. Your doctor will tell you whether Tramadol/Paracetamol is suitable for you.
- 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/Paracetamol may be altered if you also take the following medicines:

- metoclopramide, domperidone or ondansetron (medicines used to treat nausea and vomiting/being sick)
- cholestyramine (medicine used to reduce cholesterol in the blood)
- ketoconazole or erythromycin (medicines used against infections).

Tramadol/Paracetamol with food, drink and alcohol

Do not drink alcohol or alcoholic drinks or medicinal products containing alcohol while you are taking Tramadol/Paracetamol, as you may feel drowsy. Tramadol/Paracetamol can be taken with food.

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/Paracetamol while you are pregnant. Check with your doctor if you become pregnant during treatment with Tramadol/Paracetamol and before taking any further tablets.

Do not take Tramadol/Paracetamol while you are breast-feeding, as small amounts of tramadol may pass into the breast-milk.

Driving and using machines

If you feel drowsy while taking Tramadol/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.

3. How to take Tramadol/Paracetamol

Your prescriber should have discussed with you, how long the course of Tramadol/Paracetamol will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Swallow the tablets whole with sufficient liquid.

Do not break or chew the tablets.

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

Use in adolescents and adults over 12 years:

The recommended dosage is to start with 2 tablets, unless otherwise prescribed by your doctor. 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.

Your doctor may increase the time between doses if:

- you are older than 75 years
- you have kidney problems
- you have liver problems.

If you think that the effect of Tramadol/Paracetamol is too strong (you feel very drowsy or have difficulty breathing) or too weak (you do not have enough pain relief), contact your doctor.

If you take more Tramadol/Paracetamol than you should

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

If you forget to take Tramadol/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/Paracetamol

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

Generally, there will be no after-effects when treatment with Tramadol/Paracetamol is stopped.

Rarely, people who have been using a medicine containing tramadol may become dependent on it, making it hard to stop taking it. If you have been taking Tramadol/Paracetamol for some time and want to stop, contact your doctor because your body may have become used to Tramadol/Paracetamol. 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 Tramadol/Paracetamol, please contact your doctor. Other side effect information is listed in section 4.

Pregnancy

Do not take Tramadol/Paracetamol if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Tramadol/Paracetamol during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Tramadol/Paracetamol while you are breastfeeding as tramadol hydrochloride passes into breast milk and will affect your baby.

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/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
- headache, shaking
- confusion, sleep disorders, mood changes (anxiety, nervousness, 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.

Rare (may affect up to 1 in 1,000 people)

- fits, uncoordinated movements
- addiction
- blurred vision
- transient loss of consciousness (syncope).

Not known (frequency cannot be estimated from the available data)

- 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:
- 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.

Unknown frequency

- dependence and addiction (see section "How do I know if I am addicted?").

Drug Withdrawal

When you stop taking Tramadol/Paracetamol, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating. How do I know if I am addicted?

If you notice any of the following signs whilst taking Tramadol/Paracetamol, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

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 Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tramadol/Paracetamol

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 after EXP. The expiry date refers to the last day of that month. This medicinal product does not require any special storage conditions. Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Tramadol/Paracetamol contains

The active substances are Tramadol hydrochloride/ Paracetamol. Each film-coated tablet contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol

The other ingredients are: Tablet core: microcrystalline cellulose, pregelatinised starch maize starch, sodium starch glycolate, magnesium stearate. Film-coating: hypromellose, titanium dioxide (E171), macrogol, yellow iron oxide (E172), polysorbate 80.

What Tramadol/Paracetamol looks like and contents of the pack

Pale yellow colour capsule shaped biconvex film-coated tablets with engraved "SP" on one side and plain on other side. They come in PVC/PVDC blister packs with Glassine paper (35 GSM) soft/temper printed aluminium foil of 10 tablets.

Marketing Authorisation Holder

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Manufacturer

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