PACKAGE LEAFLET: INFORMATION FOR THE PATIENT
Tramadol Hydrochloride 50mg Capsules

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

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

1 What Tramadol is and what is it used for
This medicine has been prescribed for you for moderate to severe pain.
It contains Tramadol 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
Do not take Tramadol if:
- You are allergic to Tramadol, opioids or any of the other ingredients of this medicine (listed in section 6)
- You have had enough alcohol to make you drunk
- You have taken other medicines such as sleeping medicines (hypnotics), pain-relievers (analgesics), other opioids or psychotropic medicines (medicines capable of affecting the mind, emotions and behaviour) (see "Other medicines and Tramadol" section)
- You are taking or have taken in the last two weeks, medicines used to treat depression called MonoAmine Oxidase Inhibitors (MAOIs) (see "Other medicines and Tramadol" section)
- If you have epilepsy and it is not adequately controlled by treatment
- It is for use in the treatment of drug withdrawal symptoms (see "Warnings and precautions" section)

Warnings and precautions
Talk to your doctor before taking Tramadol:
- If you have a history of epilepsy or are prone to seizures, as the risk of fits (convulsions) may be increased if your dose of Tramadol exceeds the maximum daily dose limit of 400mg or if you are taking Tramadol together with medicines which lower the body's seizure threshold (see "Other medicines and Tramadol" section)
- If you suffer from:
  - A head injury, a rise in pressure inside the skull that can result from or cause brain injury (increased intracranial pressure) or reduced consciousness
  - Disorders of the respiratory centre (control of breathing), respiratory function (ability to breathe) or respiratory depression (where your breathing becomes slower or weaker than usual)
  - Severe impairment of liver and/or kidney function

- Sleep-related breathing disorders as Tramadol 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.
- Shock (pale face, cold/clammy skin, fast/shallow breathing, rapid/weak pulse, yawning, sighing and in extreme cases unconsciousness)
- Suffer from depression and you are taking antidepressants as some of them may interact with Tramadol (see 'Other medicines and Tramadol).

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').

Talk to your prescriber before taking this medicine if you:
- experience any of the following symptoms while taking Tramadol: 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.
- 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 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.

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.

<u>Tolerance, dependence, and addiction</u>
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 [product name] 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 [product name] 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, 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.

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.

Other medicines and Tramadol
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Medicines which **may interact with or be affected by** Tramadol:
- MonoAmine Oxidase Inhibitors (MAOIs), medicines used to treat depression such as moclobemide. Tell your doctor if you have taken one in the past 2 weeks
- CNS depressants, medicines used to treat anxiety and sleep disorders such as valium
- Selective Seratonin Re-uptake Inhibitors (SSRIs), medicines used to treat depression such as citalopram
- Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs), medicines used to treat mood and nerve disorders such as venlafaxine
- Tricyclic antidepressants, medicines used to treat depression such as amitriptyline

The risk of side effects increases, if you are taking certain antidepressants, Tramadol may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects').
- Medicines which lower the body's seizure threshold e.g. bupropion, mirtazapine, tetrahydrocannabinol
- Carbamazepine, a medicine used to treat and prevent fits [seizures] (anticonvulsant)
- Coumarin derivatives e.g. warfarin, a medicine used to thin the blood (anticoagulant)
- Ketoconazole, a medicine used to treat fungal infections (antifungal)
- Erythromycin, a medicine used to treat bacterial infections (antibiotic)
- Ondansetron, a medicine used to prevent feeling and being sick [nausea and vomiting] (5HT 3-receptor antagonist)
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)
- Other pain relievers such as morphine and codeine (also as cough medicine) while you are taking tramadol. You may feel drowsier or feel that you might faint. If this happens tell your doctor
- 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

Concomitant use of Tramadol and sedative medicines such as tranquillizers, benzodiazepines or other related medicines increases the risk of drowsiness, difficulties in breathing (respiratory depression) e.g. opioids, coma or 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 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.

Taking Tramadol with food and drink and alcohol
- These capsules can be taken with or without food
- During treatment with Tramadol, it is recommended not to drink alcohol

Pregnancy, Breast−feeding and Fertility
Do not take Tramadol 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 during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breast−feeding
Do not take Tramadol while you are breastfeeding as Tramadol passes into breast milk and will affect your baby.

Fertility
Based on human experience, Tramadol is suggested not to influence female or male fertility.

Driving and using machines
Tramadol may cause drowsiness, sleepiness (somnolence) or dizziness. This is more likely to occur if you drink alcohol or are taking CNS depressants (see “Other medicines and Tramadol” section). If any of these symptoms are experienced, it may be necessary to avoid driving or operating machinery or pursuing any activity in which full attention is required.

This 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 contains Sodium
This medicine contains less than 1 mmol sodium (23mg) per capsule, that is to say essentially "sodium-free".

3 How to take Tramadol
Always take Tramadol exactly as your doctor has told you. 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, 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).

- These capsules are to be taken orally with a little water
- These capsules should be swallowed whole (not divided or chewed)
- These capsules can be taken with or without food

The dose of Tramadol should be adjusted according to the intensity of your pain and your individual pain sensitivity. The lowest dose possible should be taken. Tramadol should not be taken for longer than absolutely necessary. If long-term treatment with Tramadol is necessary, careful and regular monitoring should be carried out.

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

Unless otherwise prescribed, Tramadol should be administered as follows:

Adults and children aged 12 years and over:
Short−term (acute) treatment of pain:
- An initial dose of 100mg is usually necessary
- This can be followed by doses of 50mg or 100mg at 4-6 hourly intervals
- The duration of treatment will depend on your clinical needs

Treatment of pain for long−term (chronic) conditions:
- The usual initial dose is 50mg
- The dose can then be gradually increased according to the severity of pain
- The need for continued treatment should be assessed at regular intervals (if necessary with breaks in treatment) as Tramadol should not be taken for longer than is absolutely necessary

A maximum daily dose of 400mg should **not** be exceeded unless under specialist medical supervision.

Use of Tramadol may lead to the development of dependence on this medicine or withdrawal symptoms (see section 2 "Warnings and precautions" and section 3, 'If you stop taking Tramadol Capsules").

Elderly people:
In elderly people (over 75 years of age) the rate at which Tramadol is excreted from the body may be delayed. Therefore, if necessary, the time interval between doses may need to be extended according to your requirements.

Patients with liver or kidney disorders or on dialysis:
- In patients with kidney and/or liver disorders, the rate at which Tramadol is excreted from the body may be delayed. Therefore, if necessary, the time interval between doses may need to be extended according to your requirements
- In patients with severe liver impairment, the time interval between doses should be extended to 12 hours
- Tramadol is **not** recommended for patients with severe kidney impairment
- Treatment with Tramadol to maintain pain relief following dialysis is not usually necessary as Tramadol is only removed very slowly by the dialysis processes

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.

Use in children (under 12 years of age):
Tramadol is **not** suitable for use in children under 12 years of age.

If you take more Tramadol than you should:
If you accidentally take too many capsules, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining capsules with you. **Symptoms of overdose include:** constriction of the pupil of the eye (miosis), being sick (vomiting), a sudden and marked drop in blood pressure (cardiovascular collapse), consciousness disorders up to coma, fits (convulsions) and respiratory depression (breathing becomes slower or weaker than usual) up to respiratory arrest (stop breathing) and death may occur. Serotonin syndrome has also been reported.
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If you forget to take Tramadol
Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, do **not** take a double dose to make up for a forgotten dose.

If you stop taking Tramadol Capsules
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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects
Like all medicines, Tramadol can cause side effects, although not everybody gets them.

Seek medical advice immediately if you develop the following symptoms:
- Allergic reactions: swelling of the face, throat or tongue, fever, difficulty in breathing, dizziness
- Difficulty breathing or dizziness, wheezing, (anaphylaxis, dyspnoea, bronchospasm)
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioneurotic oedema)

Very common side effects (may affect more than 1 in 10 people)
- Feeling sick (nausea)
- Dizziness

Common side effects (may affect up to 1 in 10 people)
- Being sick (vomiting)
- Constipation
- Dry mouth
- Headache
- Sleepiness or drowsiness (somnolence)
- Tiredness, weakness or lack energy (fatigue)
- Excessive sweating (hyperhidrosis)

Uncommon side effects (may affect up to 1 in 100 people)
- Low blood pressure when changing position (postural hypotension)
- A sudden and marked drop in blood pressure (cardiovascular collapse)
- Dry heaving (retching)
- A feeling of pressure in the stomach or bloating
- Diarrhoea
- Severe itching (pruritis)
- Skin rashes
- Skin rashes with the formation of wheals (urticaria)

Rare side effects (may affect up to 1 in 1000 people)
- Increase in blood pressure
- Slower heartbeat (bradycardia)
- Blurred vision
- Constriction of the pupil of the eye (miosis)
- Dilation of the pupil of the eye (mydriasis)
- Changes in appetite
- Muscle weakness
- Tingling or numbness in the hands or feet (paraesthesia)
- Shakiness (tremor)
- Seizures, convulsions [fits] (epileptiform) (see section 2, “Warnings and precautions”)
- Involuntary muscle contractions
- Unusual co-ordination
- Fainting (syncope)
- Speech disorders
- Respiratory depression (where your breathing becomes slower or weaker than usual) (see section 2, “Warnings and precautions”)
- Difficulty in breathing (dyspnoea)
- Seeing or hearing things that are not real (hallucinations)
- Sleep disturbances
- Confusion (including delirium)

- Anxiety
- Nightmares
- Mental and emotional conditions may occur following the use of Tramadol and will vary in severity depending on your personality and length of treatment. These include mood changes (usually elation but occasionally depression or discontent [dysphoria]), decrease or increase in activity and changes in cognitive and sensory abilities such as decision making, or perception disorders
- Painful urination (dysuria) or urinary retention
- Reddening of the face (flushing)
- Low blood pressure causing dizziness or lightheadedness after a change in position i.e. when standing up from a lying or sitting position (orthostatic hypotension)

Other side effects (frequency not known)
- 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 co-ordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea) (see section 2 'What you need to know before you take Tramadol").
- Increase in liver enzymes (detected through blood test)
- Low blood sugar levels (hypoglycaemia)
- Worsening of asthma
- Blood disorders
- Dependence, abuse and withdrawal reactions (see section 3, 'If you stop taking Tramadol Capsules")
- Dependence and addiction (see section "How do I know if I am addicted")
- Hiccups

Drug Withdrawal
When you stop taking Tramadol, 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, 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 at 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
- 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/blister after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- 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 to protect the environment.

6 Contents of the pack and other information

What Tramadol contains:
Each capsule contains 50mg of Tramadol Hydrochloride.

The **other ingredients** are: calcium hydrogen phosphate dihydrate, sodium starch glycollate (type A), magnesium stearate.
The **capsule shell** consists of: titanium dioxide (E171), yellow ferric oxide (E172), gelatin, indigotin (E132), Sodium Lauryl Sulfate (SLS)

What Tramadol looks like and contents of the pack:
Tramadol are hard gelatin capsules with a green cap and yellow body containing a white odourless powder.

Tramadol is available in:
Tramadol capsules are available in packs of 10, 28, 30, 56 or 100 capsules.

Not all pack sizes may be marketed.

Product Licence Number:
PL 11311/0084

Marketing Authorisation Holder and Manufacturer:
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