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Package leaflet: information for the user

Tramadol Hydrochloride 50mg Capsules, hard

(Tramadol hydrochloride)

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 it is used for

The full name of your medicine is Tramadol Hydrochloride 50mg capsules, hard. It is referred to as Tramadol in the rest of this leaflet.

Tramadol - the active substance is Tramadol hydrochloride - is a painkiller belonging to the class of opioids that acts on the central nervous system. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

Tramadol is used for the treatment of moderate to severe pain.

This medicine has been prescribed for you for the treatment of moderate to severe pain. 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 them suddenly. Your prescriber should have explained how long you will be taking them 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 or any of the other ingredients of this medicine (listed in section 6);
- in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions);
- if you are also taking MAO inhibitors (certain medicines used for treatment of depression) or have taken them in the last 14 days before treatment with Tramadol (see "Other medicines and Tramadol");
- if you are an epileptic and your fits are not adequately controlled by treatment;
- as a substitute in drug withdrawal.

Warnings and precautions
Talk to your doctor before taking Tramadol

- if you think that you are addicted to other pain relievers (opioids),
- if you suffer from consciousness disorders (if you feel that you are going to faint);
- if you are in a state of shock (cold sweat may be a sign of this);
- if you suffer from increased pressure in the brain (possibly after a head injury or brain disease);
- if you have difficulty in breathing;
- if you have a tendency towards epilepsy or fits because the risk of a fit may increase;
- if you suffer from a liver or kidney disease;
- if you are or have ever been addicted to opioids, alcohol, prescription medicines or illegal drugs.
- if you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- if you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see "other medicines and Tramadol)
- if you 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.

Sleep-related breathing disorders
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.

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").

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.

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.

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 opioids, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Epileptic fits have been reported in patients taking tramadol at the recommended dose level. The risk may be increased when doses of tramadol exceed the recommended upper daily dose limit (400 mg).

Please note that Tramadol may lead to physical and psychological addiction. When Tramadol is taken for a long time, its effect may decrease, so that higher doses have to be taken (tolerance development). In patients with a tendency to abuse medicines or who are dependent on medicines, treatment with Tramadol should only be carried out for short periods and under strict medical supervision.

Please also inform your doctor if one of these problems occurs during Tramadol treatment or if they applied to you in the past.

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.

Talk to your doctor or pharmacist or nurse 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.

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

Tramadol should not be taken together with MAO inhibitors (certain medicines for the treatment of depression).

The pain-relieving effect of Tramadol may be reduced and the length of time it acts may be shortened, if you take medicines which contain

- carbamazepine (for epileptic fits);
- ondansetron (prevents nausea).

Your doctor will tell you whether you should take Tramadol, and which dose.

The risk of side effects increases,

- if you are taking other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking Tramadol. You may feel drowsier or feel that you might faint. If this happens tell your doctor.
- Concomitant use of Tramadol and tranquillizers or sleeping pills (e.g. benzodiazepines), 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 together with sedating medicines the dose and the duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedating 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 at the same time. Your doctor will tell you whether Tramadol is suitable for you.
- if you are taking certain antidepressants, Tramadol may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects')
- if you are taking coumarin anticoagulants (medicines for blood thinning), e.g. warfarin, together with Tramadol. The effect of these medicines on blood clotting may be affected and bleeding may occur.

Tramadol with food and alcohol
Do not drink alcohol during treatment with Tramadol as its effect may be intensified. Food does not influence the effect of Tramadol.

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.

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.

There is very little information regarding the safety of tramadol in human pregnancy. Therefore you should not use Tramadol if you are pregnant.

Chronic use during pregnancy may lead to withdrawal symptoms in newborns.

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

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

Driving and using machines
Tramadol may cause drowsiness, dizziness and blurred vision and therefore may impair your reactions. If you feel that your reactions are affected, do not drive a car or other vehicle, do not use electric tools or operate machinery.

This medicine can affect your ability to drive as it may 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 medicines contains less than 1 mmol sodium (23mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Tramadol

Your prescriber should have discussed with you, how long the course of Tramadol 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 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. Do not take more than 400 mg Tramadol hydrochloride daily, except if your doctor has instructed you to do so.

Unless otherwise prescribed by your doctor, the usual dose is:

Adults and adolescents from the age of 12 years
One or two Tramadol (equivalent to 50 mg – 100 mg Tramadol hydrochloride)
Depending on the pain the effect lasts for about 4-8 hours.
Your doctor may prescribe a different, more appropriate dosage of Tramadol if necessary.

Children
Tramadol 50 mg Capsules are not suitable for children below the age of 12 years.

Elderly patients
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. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

How and when should you take Tramadol?
Tramadol capsules are for oral use. Always swallow Tramadol capsules whole, not divided or chewed, with sufficient liquid, preferably in the morning and evening. You may take the capsule on an empty stomach or with meals.

How long should you take Tramadol?
You should not take Tramadol for longer than necessary. If you need to be treated for a longer period, your doctor will check at regular short intervals (if necessary with breaks in treatment) whether you should continue to take Tramadol and at what dose.

If you have the impression that the effect of Tramadol is too strong or too weak, talk to your doctor or pharmacist.

If you take more Tramadol than you should
If you have taken an additional dose by mistake, this will generally have no negative effects. You should take your next dose as prescribed.

If you (or someone else) swallow a lot of Tramadol at the same time you should go to hospital or call a doctor straight away. Signs of an overdose include very small pupils, being sick, fall in blood pressure, fast heartbeat, collapse, unconsciousness, fits and breathing difficulties or shallow breathing.

If you forget to take Tramadol
If you forget to take the capsule, pain is likely to return. Do not take a double dose to make up for forgotten individual doses, simply continue taking the capsule as before.

If you stop taking Tramadol
If you interrupt or finish treatment with Tramadol too soon, pain is likely to return. If you wish to stop treatment on account of unpleasant effects, please tell your doctor.

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 is stopped. However, on rare occasions, people who have been taking Tramadol for some time may feel unwell if they abruptly stop taking them. 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 get panic attacks, hallucinations, unusual perceptions such as itching, tingling and numbness, and "ringing" in the ears (tinnitus). Further unusual CNS symptoms, i.e. confusion, delusions, change of perception of the own personaility (depersonalisation), and change in perception of reality (derealisation) and delusion of persecution (paranoia) have been seen very rarely. If you experience any of these complaints after stopping Tramadol, please consult your doctor.

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

Pregnancy
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.

Do not take Tramadol while you are breast-feeding 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.

You should see a doctor immediately if you experience symptoms of an allergic reaction such as swollen face, tongue and/or throat, and/or difficulty swallowing or hives together with difficulties in breathing.

The most common side effects during treatment with Tramadol are nausea and dizziness, which occur in more than 1 in 10 people.

Very common: may affect more than 1 in 10 people
- dizziness
- feeling sick (nausea)

Common: may affect up to 1 in 10 people
- headaches, drowsiness
- fatigue
- constipation, dry mouth, being sick (vomiting),
- sweating (hyperhidrosis)

Uncommon: may affect up to 1 in 100 people
- effects on the heart and blood circulation (pounding of the heart, fast heartbeat, feeling faint or collapse). These adverse effects may particularly occur in patients in an upright position or under physical strain.
- urge to sick (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhoea
- skin reactions (e.g. itching, rash)

Rare: may affect up to 1 in 1,000 people
- allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin) and shock (sudden circulation failure) have occurred in very rare cases.
- slow heartbeat
- increase in blood pressure
- abnormal sensations (e.g. itching, tingling, numbness), trembling, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), speech disorders.
- epileptic fits have occurred mainly at high doses of Tramadol or when Tramadol was taken at the same time as other medicines which may induce fits.
- changes in appetite
- hallucination, confusional state, sleep disorders, delirium, anxiety and nightmares
- psychological complaints may appear after treatment with Tramadol. Their intensity and nature may vary (according to the patient's personality and length of therapy). These may appear as a change in mood (mostly high spirits, occasionally irritated mood), changes in activity (usually suppression, occasionally increase) and decreased cognitive and sensory perception (being less aware and less able to make decisions, which may lead to errors in judgement).
- drug dependence may occur. When treatment is stopped abruptly, signs of withdrawal may appear (see "if you stop taking Tramadol")
- blurred vision, excessive dilation of the pupils (mydriasis), constriction of the pupil (miosis).
- slow breathing, shortness of breath (dyspnoea)
- worsening of asthma has been reported, however it has not been established whether it was caused by Tramadol. If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down.
- weak muscles
- passing urine with difficulty or pain, passing less urine than normal (dysuria).

Very rare: may affect up to 1 in 10,000 people
- hepatic enzyme increased

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

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, pharmacist or nurse. 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 out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and the blister. 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 protect the environment.

6. Contents of the pack and other information

What Tramadol capsules contain
The active substance is Tramadol hydrochloride.
Each hard gelatin capsule contains 50mg of the active ingredient.

The other ingredients are Microcrystalline cellulose, Pregelatinised starch, Sodium starch glycolate, Magnesium stearate, Colloidal silicon dioxide, Hard gelatin capsule.

Capsule shell contains: Gelatin, Iron oxide yellow (E172), Titanium dioxide (E171), Purified water and Edible printing ink.

Edible printing ink contains: Shellac, Black iron oxide (E172)

What Tramadol capsules look like and contents of the pack
Hard gelatin Size "4" capsules with Yellow Opaque colour cap and body containing white to off white coloured granules.

White opaque PVC/PVDC blister packs with plain aluminium foil of 10 capsules.
Pack sizes: 10, 20, 30, 50 or 100 capsules
Not all pack sizes may be marketed

Marketing Authorisation Holder
Somex Pharma, Ilford, Essex, IG3 8BS.UK

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