Package leaflet: Information for the user

Tramadol Aurobindo 50 mg 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 Aurobindo is and what it is used for

Tramadol hydrochloride - the active substance in Tramadol Aurobindo - 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 Aurobindo is used for the treatment of moderate to severe pain.

You must talk to a doctor if you do not feel better or if you feel worse after number of days.

2. What you need to know before you take Tramadol Aurobindo

Do not take Tramadol Aurobindo
- if you are allergic to active substance or any of the other ingredients of this medicine (listed in section 6).
- if you are under the influence of alcohol or sedative drugs including sleeping pills, other pain-killers or tranquiliser medicines
- if you are taking, or have taken in the last two weeks, certain medicines called “monoamine oxidase inhibitors” or MAOIs (used to treat e.g. depression, and the antibiotic linezolid). The combination could result in a serious, potentially life threatening interaction
- if you have epilepsy that is not controlled with your current medicine;
- as a substitute in drug withdrawal.

Warnings and precautions
Talk to your doctor or pharmacist before taking Tramadol Aurobindo

- if you suffer from epilepsy or seizures (fits) or have had them in the past because tramadol could increase the risk of you having further fits
- if you have liver or kidney problems.

- Suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Tramadol Aurobindo').
- 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').

As with all painkillers of this type (opioid analgesics), tramadol should be used with caution, and only under medical supervision in seriously ill patients including those with breathing difficulties, excessively low blood pressure (shock), decreased consciousness, serious head injury or brain diseases that may cause elevated pressure in the skull.

Tolerance, dependence, and addiction

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 Tramadol Aurobindo 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 Tramadol Aurobindo 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 Aurobindo, 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 Aurobindo).

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.

Sleep-related breathing disorders

Tramadol Aurobindo 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.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Tramadol Aurobindo:

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.

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.

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

Do not take Tramadol Aurobindo at the same time as medicines called "monoamine oxidase inhibitors" or MAOIs (which are used to treat e.g. depression), or if you have taken MAOIs in the past 2 weeks.

The pain-relieving effect of Tramadol Aurobindo may be weakened and/or shortened if you also take medicines containing:
- carbamazepine (used to treat epilepsy)
- pentazocine, nalbuphine or buprenorphine (pain killers)
- ondansetron (used to stop you feeling sick).

The risk of side effects increases if you take Tramadol Aurobindo at the same time as:

- 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 Aurobindo at the same time. Your doctor will tell you whether Tramadol Aurobindo is suitable for you.
- if you are taking certain antidepressants. Tramadol Aurobindo may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects').
- sedative medicines such as tranquillizers, sleeping pills, antidepressants and other pain relievers (morphine, codeine); you may feel excessively drowsy or feel that you might faint
- medicines that prevent blood clotting, such as warfarin; the dose of these medicines may need to be reduced, otherwise there could be an increased risk of potentially serious bleeding.
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)

Concomitant use of Tramadol Aurobindo 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 does prescribe Tramadol Aurobindo 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.

Tramadol Aurobindo with food and,drink and alcohol
You should not drink alcohol during treament with Tramadol Aurobindo, as its effect may be intensified.

Pregnancy and breast-feeding
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.

Pregnancy
There is very little information regarding the safety of tramadol during pregnancy. Tramadol should therefore not be used during pregnancy. If you become pregnant you should inform your doctor as soon as possible.

Breast-feeding
Tramadol is excreted into breast milk. For this reason, you should not take Tramadol Aurobindo more than once during breast-feeding, or alternatively, if you take Tramadol Aurobindo 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 Aurobindo may cause side effects such as sleepiness and dizziness. If this happens, do not drive or operate machinery.

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

3. How to take Tramadol Aurobindo

Always take this medicine exactly as your doctor or pharmacist 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 Aurobindo, 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).

The capsules should be swallowed whole with a glass of water.
The capsules can be taken with or without food and should not be chewed.

The usual doses are given below. Your doctor may gradually increase or decrease your dose depending on how you respond to the treatment.
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.

Adults and adolescents aged 12 and over
The usual dose is 50 mg or 100 mg (1 or 2 capsules) every 4-6 hours, according to severity of pain. You should normally not take more than 400 mg (8 capsules) a day.

Children below 12 years of age

Tramadol Aurobindo is not recommended for use in children below age 12.

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

If you take more Tramadol Aurobindo than you should
If you have taken more capsules than you have been told to take, contact your doctor immediately or go to your nearest hospital casualty department. A number of symptoms may occur, which might include: vomiting (being sick), a fall in blood pressure, a fast heartbeat, collapse, fainting or even coma, epileptic fits and difficulties in breathing.

If you forget to take Tramadol Aurobindo
If you forget to take Tramadol Aurobindo take it as soon as you remember and then carry on as before.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Tramadol Aurobindo
If you stop taking Tramadol Aurobindo, your pain may return.
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).

If you would like to stop treatment because you have unpleasant side effects, please talk to your doctor. If you have been taking this medicine for a very long time, you may get the following side effects if you suddenly stop treatment: restlessness, anxiety, nervousness, shaking or an upset stomach. If you get any of these effects after stopping treatment with Tramadol Aurobindo please talk to your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tramadol can occasionally cause allergic reactions although serious allergic reactions (including anaphylaxis and angioedema) are rare. Contact a doctor or emergency unit immediately if you experience any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body). The same applies in case of seizures ("fits").

The frequency of side effects is classified as follows:
Common: may affect up to 1 in 10 people
Uncommon: may affect up to 1 in 100 people
Rare: may affect up to 1 in 1,000 people
Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data

The following side effects may occur:

Very common: nausea; dizziness.

Common: headache, sleepiness; vomiting (being sick), constipation, dry mouth; sweating.

Uncommon: Irregular, rapid beating or pulsation of the heart, increased heartbeat, low blood pressure (especially when standing upright), this may lead to collapse. These adverse effects may particularly occur in patients in an upright position or under physical strain. Diarrhoea, retching, gastrointestinal irritation (a feeling of pressure in the stomach, bloating); skin disorders (e.g. itchiness, rash, sudden onset of skin redness).

Rare: Slow heartbeat, rise in blood pressure; change in appetite, tingling skin sensation (e.g. pins and needles); trembling, breathing difficulties, epileptic-like seizures ("fits"), uncoordinated movement, muscle twitches, fainting; blurred vision, dilation of pupils (mydriasis), constriction of pupils (miosis); difficulty in passing urine and urinary retention. Muscle weakness. Generalized allergic reactions (e.g. anaphylaxis and angioedema, see below). Hallucinations, confusion, anxiety, sleep disturbance and nightmares, changes in mood (high or low spirits), changes in activity (slowing down but sometimes an increase in activity) and being less aware and less able to make decisions, which may lead to errors in judgement.

Not known: Increased levels of liver enzymes. Worsening of asthma has been reported, however it has not been established whether it was caused by tramadol. Speech disorders, 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 Aurobindo').

During use of Tramadol Aurobindo, dependence, abuse and addiction may occur. When treatment is stopped, symptoms of withdrawal reactions may occur, such as agitation, anxiety, nervousness, sleeplessness, uncontrolled muscular action (hyperkinesia), tremor and gastrointestinal symptoms. Other symptoms that have very rarely been seen with tramadol discontinuation e.g., panic attacks, severe anxiety, hallucinations, tingling skin sensation, hearing sounds e.g. ringing or buzzing, without an external cause (tinnitus).

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Tramadol Aurobindo

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, bottle after EXP. The expiry date refers to the last day of that month.

Store below 30ºC.

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 Aurobindo contains
The active substance is tramadol hydrochloride. Each hard capsule contains 50 mg tramadol hydrochloride.

The other ingredients are:
Capsule contents: Cellulose, microcrystalline, silica colloidal anhydrous, sodium starch glycolate (Type A), magnesium stearate.

Capsule shell: Gelatin, sodium lauryl sulphate, Indigo carmine, iron oxide yellow (E172) and titanium dioxide (E171).

Printing ink: Shellac and black iron oxide (E172).

What Tramadol Aurobindo looks like and contents of the pack
Green /Yellow, size '4' hard gelatin capsules filled with white to off-white powder and imprinted with 'T' on green cap and '02' on yellow body with black ink.

PVC/PVDC/Aluminium foil blister*:* 10, 20, 30, 50, 60, 90, 100 and 500 Capsules
HDPE bottle pack with polypropyle closure*:* 30,200 and 500 Capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Aurobindo Pharma (Malta) Limited
Vault 14, Level 2, Valletta Waterfront,
Floriana FRN 1913
Malta

Manufacturer
APL Swift Services (Malta) Limited
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