

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Tramadol HCl Aurobindo Retard 100 mg, 150 mg, 200 mg,  
prolonged-release tablets

tramadol hydrochloride

Read the entire 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.

Do you have any questions? Contact your doctor or pharmacist.

Do not pass this medicine on to others. It has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.

Do you experience any side effects not listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

### Contents of this leaflet

1. What is Tramadol HCl Aurobindo Retard and what is it used for?
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## 1. WHAT IS TRAMADOL HCL AUROBINDO RETARD AND WHAT IS IT USED FOR?

Tramadol HCl Aurobindo Retard is a painkiller. Tramadol HCl Aurobindo Retard reduces pain by inhibiting certain chemical substances in the central nervous system (in the brain and spinal cord).

Tramadol HCl Aurobindo Retard can be used by adults and adolescents over 12 years. It is used for the treatment of moderate to severe pain. Tramadol HCl Aurobindo Retard is not suitable for children under 12 years.

## 2. WHEN SHOULD YOU NOT TAKE THIS MEDICINE OR BE EXTRA CAUTIOUS?

When should you not use this medicine?

if you are hypersensitive to Tramadol or other components of Tramadol HCl Aurobindo Retard

in case of an overdose with alcohol, sleeping pills, painkillers, opiates, or other medicines that work through the brain (psychotropic drugs)

when using certain medicines for depression (the so-called MAO inhibitors), or if these have been used in the last 14 days

if you suffer from epilepsy that is not treated with medication

for the treatment of withdrawal symptoms in drug addicts.

When should you be extra cautious with this medicine?

if you have recently had head injuries or increased pressure in the head (e.g., after an accident)  
if you suffer from consciousness disorders (if you feel like fainting)  
if you suffer from kidney or liver disorders (see section 3 "How to take this medicine?")  
if you suffer from respiratory disorders  
if you are prone to epilepsy or seizures, as the risk of an attack may increase.  
if you suffer from shock (cold sweat can be a sign of this)  
if you suffer from depression and use antidepressants, as some of these medicines can interact with tramadol (see "Are you taking any other medicines?")  
if you also use other (medicinal) products that work through the brain, including alcohol.

#### Tolerance, dependence, and addiction

This medicine contains tramadol, which belongs to a group of strong painkillers called opiates. Repeated use of opiates can lead to the medicine becoming less effective (you become accustomed to it; this is also called tolerance). Repeated use of Tramadol HCl Aurobindo Retard can also lead to dependence, misuse, and addiction, which can result in a life-threatening overdose. The risk of these side effects may increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel like you have no control over how much medication 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 be at greater risk of becoming dependent on or addicted to Tramadol HCl Aurobindo Retard if:

- you or someone in your family has ever misused or been addicted to alcohol, prescription drugs, or illegal drugs ("addiction");
- you smoke;
- you have ever had mood problems (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following symptoms while using Tramadol HCl Aurobindo Retard, it may be a sign that you have become dependent or addicted:

You need to take the medication longer than your doctor has advised.

You need to take more than the recommended dose.

You use the medication for reasons other than prescribed, for example, 'to stay calm' or 'to help you sleep'.

You have made repeated, unsuccessful attempts to stop using the medication or to control its use.

When you stop taking the medication, you feel unwell and feel better when you take the medication again ('withdrawal symptoms').

If you notice any of these symptoms, contact your doctor to discuss the best treatment plan for you. This includes discussing when the right time is to stop and how to stop safely (see section 3, If you stop taking this medicine).

#### Sleep-related breathing disorders

Tramadol HCl Aurobindo Retard can cause sleep-related breathing disorders, such as sleep apnea (breathing pauses during sleep) and sleep-related hypoxemia (low oxygen levels in the blood). Possible complaints include: breathing pauses during sleep, waking up at night due to

shortness of breath, difficulty staying asleep, or excessive daytime sleepiness. If you or someone else notices these complaints, contact your doctor. Your doctor may consider a dose reduction.

Contact your doctor or pharmacist if you experience the following symptoms while taking this medicine

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 complaints, contact your doctor. Your doctor will decide if you need to take hormone supplements.

After long-term treatment (> 3 months), headaches may develop or worsen. When tramadol has been used to treat tension or cluster headaches or migraines (which is not a registered use of tramadol), cases of medication overuse headache (MOH) have been reported.

Tramadol is converted in the liver by an enzyme. Some people have a variation of this enzyme, and this can affect them in different ways. In some people, pain relief may be insufficient, while others may experience severe side effects. If you notice one or more of the following symptoms, you should stop taking the medication and consult a doctor immediately: slow or shallow breathing, confusion, drowsiness, constricted pupils, nausea or vomiting, constipation, and lack of appetite.

There is a small risk that you may experience a so-called serotonin syndrome, which can occur after using tramadol alone or in combination with certain antidepressants. Consult a doctor immediately if you experience any of the symptoms of this serious syndrome (see section 4 "Possible side effects").

Epileptic seizures have been reported in patients using tramadol at the recommended dose. The risk may be increased when the dose of tramadol exceeds the recommended daily dose limit (400 mg).

Children and adolescents up to 18 years

Use in children with breathing problems

Tramadol is not recommended for children with breathing problems, as the symptoms of tramadol poisoning can be more severe in these children.

Are you using any other medicines?

Inform your doctor or pharmacist if you are using or have recently used other medicines. This also applies to medicines that you can obtain without a prescription.

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

The pain-relieving effect of Tramadol HCl Aurobindo Retard may be reduced or last less long if you are also using medicines containing the following active ingredients:

carbamazepine (used to treat epilepsy)

ondansetron (used to stop nausea).

The chance of side effects increases if you take Tramadol HCl Aurobindo Retard simultaneously with:

sedatives, such as tranquilizers, sleeping pills, antidepressants, and strong painkillers (morphine, codeine, pethidine). You may feel excessively sleepy or feel like you are going to faint

blood thinners, such as warfarin. The dosage of these medicines may need to be reduced, otherwise there is an increased risk of bleeding

medicines that can lead to convulsions (seizures), such as certain antidepressants or antipsychotics. The risk of a seizure may increase if you use Tramadol HCl Aurobindo Retard simultaneously. Your doctor will tell you if Tramadol HCl Aurobindo Retard is suitable for you

certain antidepressants. Tramadol HCl Aurobindo Retard can interact with these medicines and you may experience serotonin syndrome (see section 4 "Possible side effects")

patients using medicines against convulsions (seizures) in combination with Tramadol HCl Aurobindo Retard have an increased risk of having convulsions (seizures). The simultaneous use of these medicines can lower the threshold for having convulsions (seizures).

Gabapentin or pregabalin for the treatment of epilepsy or pain due to nerve problems (neuropathic pain)

Simultaneous use of Tramadol inhibitors and sedatives, such as benzodiazepines or related medicines, increases the risk of drowsiness, breathing problems (respiratory depression), coma and can be life-threatening. Therefore, simultaneous use should only be considered if other treatment options are not possible.

However, if your doctor prescribes Tramadol Retard together with sedative medicines, the dose and duration of the simultaneous treatment should be limited by your doctor. Inform your doctor about all sedative medications you are using and follow your doctor's dosage recommendation closely. It may be helpful to inform friends or family members about the symptoms mentioned above. Contact your doctor if you experience such symptoms.

What should you watch out for with food and alcohol?

Tramadol HCl Aurobindo Retard should never be used in combination with alcohol. Food does not affect the effect of Tramadol HCl Aurobindo Retard.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medication.

Pregnancy

Consult your doctor or pharmacist before taking any medications.

Tramadol crosses the placenta. There is insufficient data on use in humans to assess potential harm. Prolonged use during pregnancy can lead to withdrawal symptoms in the newborn, as a consequence of addiction. Therefore, tramadol should not be used during pregnancy. Your doctor will advise you.

Breastfeeding

Consult your doctor or pharmacist before taking any medications.

Tramadol is excreted in breast milk. For this reason, you should not take Tramadol HCl Aurobindo Retard more than once while breastfeeding or, if you take Tramadol HCl Aurobindo Retard more than once, you should stop breastfeeding.

### Fertility

Based on human experience, it is suggested that tramadol does not affect female or male fertility.

### Driving and using machines

Tramadol HCl Aurobindo Retard can cause drowsiness, dizziness, and blurred vision and can therefore affect your reactions. If you feel your reactions are affected, do not drive a car or other vehicle, do not use electric tools, and do not operate machines.

## 3. HOW TO TAKE THIS MEDICINE?

Strictly follow your doctor's instructions on the use of Tramadol HCl Aurobindo Retard. If you are not sure, consult your doctor or pharmacist.

Before starting treatment and at regular intervals during treatment, your doctor will discuss with you what to expect from using Tramadol HCl Aurobindo Retard, when and how long you should take it, when to contact your doctor, and when to stop using it (see also section 2).

### Dosage

The dose is adjusted to the severity of your pain and your personal sensitivity to pain. In general, the lowest dose that relieves the pain should be used.

Do not take more than 400 mg of tramadol hydrochloride per day, unless your doctor has instructed you to do so.

The usual dosage is:

Adults and children over 12 years:

The initial dosage is:

Tramadol HCl Aurobindo Retard 100 mg: 1 tablet (100 mg tramadol hydrochloride), 2 times daily in the morning and evening.

Thereafter, if pain relief is insufficient, the dose can be increased to:

Tramadol HCl Aurobindo Retard 150 mg: 1 tablet (150 mg tramadol hydrochloride), 2 times daily in the morning and evening or

Tramadol HCl Aurobindo Retard 200 mg: 1 tablet (200 mg tramadol hydrochloride), 2 times daily in the morning and evening.

If the dose prescribed to you cannot be achieved with this tablet strength, other strengths of this medicine are available to achieve the dose.

### Children

Tramadol HCl Aurobindo Retard is not suitable for children under 12 years.

### Elderly

In elderly patients (over 75 years), the excretion of tramadol may be delayed. If this applies to you, your doctor may recommend increasing the interval between doses.

Severe liver or kidney disease (insufficiency) / dialysis patients

Patients with severe liver and/or kidney insufficiency should not use Tramadol HCl Aurobindo Retard. If there is mild or moderate insufficiency, your doctor may advise increasing the interval between doses.

#### Method of administration

Tramadol HCl Aurobindo Retard is a tablet with a special core to release the active substance slowly and over a longer period in the body. As a result, it may take a little longer before you notice an effect.

Swallow the tablet whole (do not chew or break) with a quantity of water. Preferably take in the morning and evening. The tablets can be taken on an empty stomach or during a meal.

#### How long should you use Tramadol HCl Aurobindo Retard?

Your doctor will tell you how long you need to use Tramadol HCl Aurobindo Retard. This depends on the cause of the pain. Do not use Tramadol HCl Aurobindo Retard longer than necessary.

If you notice that Tramadol HCl Aurobindo Retard is too strong or not strong enough, consult your doctor or pharmacist.

#### Have you taken too much of this medicine?

If you accidentally take an extra dose, it generally has no negative effects. You should take your next dose as prescribed.

If you (or someone else) swallow a lot of this medicine, you should go to the hospital immediately or call a doctor. Signs of an overdose include very small pupils, vomiting, low blood pressure, rapid heartbeat, collapse, unconsciousness, seizures, and breathing difficulties or shallow breathing.

#### Have you forgotten to take this medicine?

If you forget to take a tablet, the pain is likely to return. Do not take a double dose to make up for the forgotten dose, but continue taking the tablets in the same way.

#### If you stop taking this medicine

When you interrupt or stop the treatment too quickly, the pain is likely to return. If you want to stop the treatment due to unwanted side effects, it is best to do so in consultation with your doctor.

In general, there is no aftereffect when the treatment with Tramadol HCl Aurobindo Retard is stopped. However, in rare cases, people who have taken Tramadol HCl Aurobindo Retard tablets for a period may feel unwell when they stop abruptly. They may feel agitated, anxious, nervous, or shaky. One may be hyperactive, have trouble sleeping, and experience stomach or intestinal disturbances. Only a few people experience panic attacks, hallucinations, unusual sensations such as itching, tingling, and numbness, and noise in the ears (tinnitus). Further unusual CNS symptoms, i.e., confusion, delusions, change in perception of one's own personality (depersonalization), and change in perception of reality (derealization) and paranoia are very rarely observed. If you experience any of these complaints after stopping Tramadol HCl Aurobindo Retard, you should consult your doctor.

Do not stop taking the medicine suddenly unless your doctor tells you to do so. If you want to stop taking this medicine, discuss it with your doctor first, especially if you have used the

medicine for a long time. Your doctor will tell you when and how you can stop, for example by gradually reducing the dose to minimize the risk of unnecessary side effects (withdrawal symptoms).

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

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Tramadol HCl Aurobindo Retard can cause side effects, although not everyone gets them.

The following side effects may occur:

Very common (may affect more than 1 in 10 users):

- dizziness
- Feeling sick (nausea).

Common (may occur in 1 in 10 users):

- headache
- confusion
- vomiting
- constipation
- dry mouth
- sweating
- drowsiness
- fatigue.

Sometimes (may occur in 1 in 100 users):

- effects on the heart and circulation (palpitations, rapid heartbeat, fainting or syncope). These side effects may particularly occur in patients who are standing upright or under physical strain.
- urge to vomit (retching), stomach discomfort (e.g., feeling of pressure in the stomach, bloating), diarrhea.
- skin reactions (e.g., itching, rash).

Rare (may occur in 1 in 1000 users):

- allergic reactions (e.g., difficulty breathing, wheezing, swelling of the skin) and shock (sudden circulatory collapse) have occurred in very rare cases.
- slow heartbeat
- increase in blood pressure
- abnormal sensations (e.g., itching, tingling, numbness), tremors, epileptic seizures, muscle twitches, uncoordinated movements, transient loss of consciousness (syncope), speech disorders.
- Epileptic seizures have mainly occurred at high doses of tramadol or when tramadol was taken simultaneously with other medications that can cause seizures.
- changes in appetite
- hallucinations, confused state, sleep disorders, delirium, anxiety, and nightmares
- Psychological complaints may occur after treatment with /.../. Their intensity and nature can vary (according to the patient's personality and the duration of therapy). These may present as a change in mood (usually elevated, sometimes irritated), changes in

activity (activity slowing but sometimes increasing), and impaired cognitive and sensory perception (less aware and less able to make decisions, which can lead to judgment errors).

Drug addiction may occur. If the treatment is stopped abruptly, withdrawal symptoms may occur (see "If you stop taking this medicine").

blurred vision, excessive dilation of the pupils (mydriasis), constriction of the pupil (miosis).

slow breathing, shortness of breath (dyspnea)

Exacerbation of asthma has been reported, but it has not been established whether this was caused by tramadol. If the recommended doses are exceeded or if other drugs that suppress brain function are taken simultaneously, breathing may slow down.

weak muscles

difficulty or pain urinating, urinating less than normal (dysuria).

Very rare: occurs in less than 1 in 10,000 people  
elevated liver enzymes

Unknown (frequency cannot be estimated from the available data):

Lowering of blood sugar levels

hiccups.

Serotonin syndrome, which may manifest as mood changes (e.g., agitation, hallucinations, coma) and other effects, such as fever, rapid heartbeat, unstable blood pressure, involuntary muscle twitching, muscle stiffness, lack of coordination, and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea) (see section 2 "When should you not take this medicine or be extra careful?").

Side effects that occur with withdrawal, identical to the withdrawal symptoms of opiates, may include: restlessness, anxiety, nervousness, insomnia, motor restlessness (hyperkinesia), tremors (tremor), and gastrointestinal disorders.

In very rare cases (occurring in less than 1 in 10,000 users), allergic reactions (e.g., difficulty breathing, wheezing, swelling of the skin), shock, and elevation of liver enzyme levels have occurred. In the case of a swollen face, tongue, and/or throat and/or difficulty swallowing or hives combined with breathing difficulties, you should consult a doctor immediately.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Dutch side effects center Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

## 5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Store this medicine in a safe and well-sealed place, where others cannot access it. It can cause serious harm and be fatal to people for whom it is not prescribed.

Do not use Tramadol HCl Aurobindo Retard after the expiry date which is stated on the box and the blister pack and/or the securitainer after "EXP.:". The expiry date refers to the last day of that month.

Store in the original package to protect from moisture.

Do not flush medicines down the sink or toilet. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

What substances are in Tramadol HCl Aurobindo Retard?

The active substance in this medicine is tramadol hydrochloride.

1 tablet Tramadol HCl Aurobindo Retard 100 mg contains 100 mg tramadol hydrochloride.

1 tablet Tramadol HCl Aurobindo Retard 150 mg contains 150 mg tramadol hydrochloride.

1 tablet Tramadol HCl Aurobindo Retard 200 mg contains 200 mg tramadol hydrochloride.

The other substances in this medicine are: calcium hydrogen phosphate dihydrate (E341), hydroxypropyl cellulose (E463), colloidal anhydrous silica (E551) and magnesium stearate (E470b).

What does Tramadol HCl Aurobindo Retard look like and what is in a pack?

Tramadol HCl Aurobindo Retard 100 mg tablets are off-white, round biconvex tablets.

Tramadol HCl Aurobindo Retard 150 mg tablets are off-white, capsule-shaped tablets.

Tramadol HCl Aurobindo Retard 200 mg tablets are off-white, capsule-shaped tablets.

Tramadol HCl Aurobindo Retard 100 mg: packs of 10, 20, 30, 50, 60, 90, 100, 120, 180 or 500 white tablets in blister packs or in plastic securitainers.

Tramadol HCl Aurobindo Retard 150 mg: packages of 10, 20, 30, 50, 60, 90, 100, 120, 180, or 500 white tablets in blister packs or in plastic securitainers.

Tramadol HCl Aurobindo Retard 200 mg: packages of 10, 20, 30, 50, 60, 90, 100, 120, 180, or 500 white tablets in blister packs or in plastic securitainer

Marketing authorization holder and manufacturer

Marketing authorization holder

Aurobindo Pharma B.V., Baarnsche Dijk 1, 3741 LN, Baarn, Netherlands

Manufacturer

FAL B.V., Dijkgraaf 30, 6921 RL, Duiven, Netherlands

Medochemie, Michalaki Erakleous Str., Agios Athanasios Industrial Area, 4101 Limassol, Cyprus

Registered under

RVG 33553: Tramadol HCl Aurobindo Retard 100 mg, prolonged-release tablets

RVG 33554: Tramadol HCl Aurobindo Retard 150 mg, prolonged-release tablets

RVG 33555: Tramadol HCl Aurobindo Retard 200 mg, prolonged-release tablets

This medicine is registered in EEA member states under the following names:

Netherlands: Tramadol HCl Aurobindo Retard 100, 150, 200 mg, prolonged-release tablets

Portugal: Tramadol Aurovitas

This leaflet was last approved in September 2024.