

## Package Leaflet: Information for the patient

### **Tramadol retard 100 mg, 150 mg and 200 mg Prolonged release tablets**

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

#### **1. What **Tramadol retard** is and what it is used for**

**Tramadol retard** is a pain killer. **Tramadol retard** eases the pain by inhibition of certain chemicals of the central nervous system (in the brain and the spinal cord).

**Tramadol retard** can be used in adults and adolescents over 12 years of age. It is used for the treatment of moderate to severe pain.

**Tramadol retard** is not suitable for children under the age of 12 years.

#### **2. What you need to know before you take **Tramadol retard****

##### **Do not take **Tramadol retard**:**

- If you are allergic to tramadol hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you have recently drunk too much alcohol or taken too many sleeping tablets, pain killers, opiates or any medicines that work via the brain (psychotropic medicines).
- When using certain medicines against depression (so-called MAO-inhibitors) or when these have been used the last 14 days.
- If you suffer from epilepsy that is not controlled by medication
- For the treatment of withdrawal symptoms in drug addicts.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking **Tramadol retard**:

- If you have recently had any head injuries, or an increased pressure in the head (e.g. after an accident).
- If you suffer from disorders of the kidneys or liver (see section 3: How to take **Tramadol retard**).
- If you suffer from difficulty to breathe.
- If you have a tendency towards epilepsy or fits because the risk of a fit may increase. Seizures 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).
- If you suffer from addiction to opiates.

- If you suffer from shock (cold sweat may be a sign of this).
- If you use other medicines or substances that work via the brain, including alcohol.

After long term treatment (>3 months) headache may develop or aggravate.

When tramadol has been used to treat tension or cluster headache or migraine (which is not a registered use for tramadol) cases have been reported of medication overuse headache (MOH).

Please note that **Tramadol retard** may lead to physical and psychological addiction. When **Tramadol retard** 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 retard** should only be carried out for short periods and under strict medical supervision.

### **Other medicines and **Tramadol retard****

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

Do not take **Tramadol retard** at the same time, or within 14 days of taking medicines called monoamine oxidase inhibitors (moclobemide or phenelzine for depression, selegiline for Parkinson's disease).

The pain relieving effect of **Tramadol retard** may be weakened and/or shortened if you also take medicines containing:

- Carbamazepine (used to treat epilepsy)
- Buprenorphine, nalbuphine, or pentazocine (pain killers)
- Ondansetron (used to stop you feeling sick)

The risk of side effects increases:

- 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 retard** at the same time. Your doctor will tell you whether **Tramadol Retard** is suitable for you.
- if you are taking certain antidepressants. **Tramadol Retard** may interact with these medicines and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C.
- if you take **Tramadol retard** at the same time as sedative medicines such as tranquillisers, sleeping pills, antidepressants and strong pain relievers (morphine, codeine, pethidine). You may feel excessively drowsy or feel that you might faint.
- if you take **Tramadol retard** at the same time as blood thinning medicines, such as warfarin. The dose of these medicines may need reducing, otherwise there could be an increased risk of serious bleeding.
- anticonvulsant drugs taken with tramadol can lower the seizure threshold and the risk of convulsions may increase in these patients.

### ****Tramadol retard** with alcohol**

Tramadol retard should not be used in combination with alcohol.

### **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

Tramadol passes the placenta. There are not enough details known to judge the possible harm in human. Long term treatment during pregnancy may lead to withdrawal symptoms in the newborn after birth, as a consequence of addiction. Therefore tramadol should not be taken during pregnancy. Your doctor will advise you.

### Breastfeeding

Generally, the use of **Tramadol retard** is not recommended during breast feeding. Small amounts of tramadol are excreted into breast milk. On a single dose it is usually not necessary to interrupt breast feeding. Please ask your doctor for advice.

### **Driving and using machines**

**Tramadol retard** can cause drowsiness and dizziness, and blurred vision. Because of this **Tramadol retard** can affect your ability to drive and operate machinery. This can be intensified by alcohol or by medicine that acts or works via the brain.

Do not drive a car or do other activities that need you to be alert, until you know how tramadol affects you. Please see section 4. 'Possible Side Effects' for a full list of possible effects that may impair alertness and coordination.

## **3. How to take **Tramadol retard****

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### Dose

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. The usual dosage is:

#### Adults and adolescents over 12 years of age

The starting dose is:

**Tramadol retard** 100 mg: one tablet (100 mg tramadol hydrochloride) twice a day.

If this is not sufficient to kill the pain the dose can be increased to:

**Tramadol retard** 150 mg: one tablet (150 mg tramadol hydrochloride) twice a day or

**Tramadol retard** 200 mg: one tablet (200 mg tramadol hydrochloride) twice a day.

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

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

### Method of administration

**Tramadol retard** is a tablet with a special core to let out the active ingredient slowly and long-lasting in the body. Because of this it can take a bit longer before you notice the effect.

Swallow the tablet whole (without chewing or breaking), with a glass of water.

Preferably administer in the morning and evening. The tablets may be taken on an empty stomach or during the meal.

### Duration of the treatment with **Tramadol retard**

Your doctor will tell you how long you should use **Tramadol retard**. This depends on the cause of the pain. Do not use **Tramadol retard** any longer than necessary.

If you notice that **Tramadol retard** is too strong or is not enough, talk to your doctor or pharmacist.

### **If you take more **Tramadol retard** than you should**

If you have taken too many **Tramadol retard** you should immediately contact your doctor, nearest hospital or clinic. The possible symptoms that may occur are: pin-point pupils, vomiting, a fall in

blood pressure, a fast heartbeat, collapse, disturbed consciousness including coma (deep unconsciousness), epileptic fits and difficulties in breathing.

#### **If you forget to take Tramadol retard**

If you forgot 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 tablets as before.

#### **If you stop taking Tramadol retard**

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

Generally there will be no after effects when treatment with Tramadol retard is stopped. However, on rare occasions, people who have been taking Tramadol retard tablets 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 noise in the ears (tinnitus). If you experience any of these complaints after stopping Tramadol retard, please consult 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, Tramadol retard tablets can cause side effects, although not everybody gets them. The following side effects can occur:

Very common (affects more than 1 user in 10): nausea and dizziness.

Common (affects 1 to 10 users in 100): headache, confusion, vomiting, constipation, dry mouth, sweating, drowsiness, fatigue.

Uncommon (affects 1 to 10 users in 1,000): heart palpitations, irregular heart beat, low blood pressure – especially when standing up, heart failure (cardiovascular collapse), uneasiness (qualm), pressure on the stomach, feeling of fullness, itch, rash and rash with severe itch and forming of lumps (hives or urticaria), diarrhea.

Rare (affects 1 to 10 users in 10,000): blurred vision, slower heartbeat than normal, increase in blood pressure, changes in appetite, itch or tingling without cause, shaking, breathing slower than normal, convulsions, hallucinations, confusion, sleep disturbances and nightmares, allergic reactions (e.g. shortness of breath), tightness of the chest by cramp of the muscles of the airways (bronchospasm), gasping, sudden fluid accumulation in the skin and mucosa (e.g. throat or tongue), breathing problems (respiration difficulties) and/or itch and hypersensitiveness. Also reported: mood changes, changes in activity, changes in the observation or the ability to make decisions, muscle weakness, difficulties passing water, involuntary muscle contractions, abnormal coordination, and fainting (syncope).

Frequency not known (cannot be estimated from the available data): Enlarged pupils. Decrease in blood sugar level.

Side effects that occur at withdrawal, identical to withdrawal symptoms with opiates, can be: agitation, anxiety, fear, nervousness, sleeplessness, difficulty keeping still (hyperkinesias), shaking (tremor) and stomach discomfort (gastro-intestinal disorders).

Allergic reaction (e.g. difficulty in breathing, wheezing, swelling of skin), shock (sudden circulation failure) and increase in liver enzyme values have occurred in very rare cases (affects less than 1 user in 10,000). **You should see a doctor immediately if you experience symptoms such as swollen face, tongue and/or throat and/or difficulty to swallow or hives together with difficulties in breathing.**

## 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 *<to be completed nationally>*. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store **Tramadol retard**

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 blister and / or bottle and the carton after “exp”. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

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 retard** contains:

The active substance is tramadol hydrochloride.

1 tablet of **Tramadol retard** 100 mg, contains 100 mg tramadol hydrochloride

1 tablet of **Tramadol retard** 150 mg, contains 150 mg tramadol hydrochloride

1 tablet of **Tramadol retard** 200 mg, contains 200 mg tramadol hydrochloride

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

What **Tramadol retard** looks like and contents of the pack

**Tramadol retard** 100 mg tablets are off white, round biconvex tablets

**Tramadol retard** 150 mg tablets are off white, capsule shaped tablets

**Tramadol retard** 200 mg tablets are off white, capsule shaped tablets

**Tramadol retard** 100 mg: packs of 10, 20, 30, 50, 60, 90, 100, 120, 180 or 500 off white tablets in blisters or in plastic tablet containers.

**Tramadol retard** 150 mg: packs of 10, 20, 30, 50, 60, 90, 100, 120, 180 or 500 off white tablets in blisters or in plastic tablet containers.

**Tramadol retard** 200 mg: packs of 10, 20, 30, 50, 60, 90, 100, 120, 180 or 500 off white tablets in blisters or in plastic tablet containers.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and manufacturer:**

*<[To be completed nationally]>*

**Manufacturers:**

*<[To be completed nationally]*

**This medicinal product is authorised in the Member States of the EEA under the following names:**

The Netherlands	Tramadol HCl Retard Duiven 100 mg, 150 mg, 200 mg
Austria	Tramadol – Actavis 100 mg, 150 mg, 200 mg Retardtabletten
Czech Republic	Tramadol – Actavis 100 mg, 150 mg, 200 mg
Poland	Travictol 100 mg, 150 mg, 200 mg
Portugal	Tramadol Actavis 100 mg, 150 mg, 200 mg omprimidos de Libertacao Prolongada
Sweden	Tramadol Retard Actavis 100 mg, 150 mg, 200 mg
Slovakia	Tramadol – Actavis 100 mg, 150 mg, 200 mg

**This leaflet was last revised in {MM/YYYY}**

<[To be completed nationally]>