

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Tramadol Hydrochloride 50 mg 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 Hydrochloride is and what it is used for
2. What you need to know before you take Tramadol Hydrochloride
3. How to take Tramadol Hydrochloride
4. Possible side effects
5. How to store Tramadol Hydrochloride
6. Contents of the pack and other information

#### 1. WHAT TRAMADOL HYDROCHLORIDE IS AND WHAT IT IS USED FOR

Tramadol is one of a group of medicines called analgesics which are more commonly known as pain killers. Tramadol acts on the brain and spinal cord to reduce the amount of pain you feel.

Tramadol is for the treatment and prevention of moderate to severe pain.

#### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRAMADOL HYDROCHLORIDE

##### Do not take Tramadol Hydrochloride

- if you are allergic to Tramadol or any of the other ingredients of this medicine (listed in section 6)

- if you have been drinking enough alcohol to make you feel even slightly drunk or have taken several doses of other medicines that affect the nervous system such as sleeping tablets, morphine-like drugs or psychotropic drugs which are used to treat schizophrenia and severe anxiety
- if you are also taking drugs known as monoamine oxidase inhibitors (for example, phenelzine and isocarboxazid), which are used to treat depression, or have been taking them within the past two weeks
- if you are suffering from uncontrolled epilepsy
- if you are undergoing narcotic withdrawal treatment

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Tramadol Hydrochloride.

- if you suffer from kidney or liver disease
- if you suffer from epilepsy or convulsions or have had them in the past
- if you suffer from asthma or have trouble breathing
- if you have had a recent head injury or increased intracranial pressure.
- if you are taking antidepressants known as selective serotonin re-uptake inhibitors (for example, fluoxetine and paroxetine) and tricyclic antidepressants (for example, amitriptyline and desipramine) or carbamazepine (used to treat epilepsy and manic-depressive illness) or lithium (used to treat mania and depression)
- if you are hypersensitive to opiates (for example morphine, codeine or similar agents)
- if you have a decreased level of consciousness
- before you have a general anaesthetic

##### Other medicines and Tramadol Hydrochloride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription.

- Tramadol suppresses the central nervous system. Concomitant administration of tramadol with other centrally acting drugs including alcohol may potentiate this depressant effect.
- Simultaneous administration of carbamazepine (anti-epilepticum) may decrease the effectiveness of tramadol.

- Tramadol may interact with lithium
- Concomitant treatment with tramadol and blood diluting drugs as warfarine can increase extravasations of blood (bruises).
- In case of concomitant administration of digoxine rare cases of toxicity signs have been observed such as nausea, vomiting and cardiac arrhythmias.
- Simultaneous administration of ritonavir (drug used to treat HIV-infection) can potentiate the respiratory depression caused by tramadol. The dose of tramadol will possibly be reduced.
- Concomitant administration of e.g. buprenorphine, nalbuphine or pentazocine and tramadol can decrease the effect of tramadol.
- 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 hydrochloride 50 mg tablets at the same time. Your doctor will tell you whether Tramadol hydrochloride 50 mg tablets is suitable for you.
  - if you are taking certain antidepressants. Tramadol hydrochloride 50 mg tablets 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.

**Tramadol Hydrochloride with food and drink**  
Not applicable

### **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.

This medicine is not recommended during pregnancy, unless your doctor considers it as necessary.

Tramadol has been found in breast milk of women using this medicine. Therefore tramadol should not be used by women breastfeeding their child.

### **Driving and using machines**

Tramadol may make you sleepy so be careful about driving or operating machinery.

The 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 Hydrochloride contains lactose**

This medicine contains 100 mg lactose per tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

## **3. HOW TO TAKE TRAMADOL HYDROCHLORIDE**

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.

#### 1) Adults and Children aged 12 years and over:

##### Acute pain (i.e. pain lasting a short time):

An initial dose of 100mg (i.e. two tablets) is usually necessary. Your doctor may advise you to take either 1 or 2 tablets after this, not more frequently than every four hours.

##### Pain associated with chronic conditions (i.e. pain lasting a long time):

Use an initial dose of 50mg (i.e. one tablet). Your doctor will advise you how much to take following this initial dose. You should never take more than 400mg (i.e. 8 tablets) in any 24 hours, unless prescribed by your doctor.

## 2) 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.

## 3) Severe liver or kidney disease (insufficiency)/dialysis patients

Patients with severe liver and/or kidney insufficiency should not take Tramadol hydrochloride 50 mg tablets. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

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

If you accidentally take more than your prescribed dose, contact your nearest hospital casualty department or tell your doctor immediately.

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

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

If you forget to take a dose, do so as soon as you remember and then go on as before.

### **If you stop taking Tramadol hydrochloride 50 mg tablets**

Stopping treatment suddenly can cause withdrawal symptoms.

If you have any further questions on the use of this product, 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 cause allergic reactions (e.g. difficulty breathing, constriction of the muscles of the bronchi, wheezing, swelling of the head and neck), serious hypersensitivity reaction (generalized allergic reaction). This occurs rarely (may affect up to 1 in 1,000 people). Stop taking Tramadol Hydrochloride 50 mg tablets and contact your doctor straight away if any of these symptoms occur.

### Other side effects

#### Very common (may affect more than 1 in 10 people)

- dizziness
- nausea

#### Common (may affect up to 1 in 10 people)

- headache, muzziness
- vomiting, constipation, diarrhoea, dry mouth
- sweating

#### Uncommon (may affect up to 1 in 100 people)

- heart palpitation, increased heart rate, postural hypotension, cardiovascular collapse
- flatulency, retching; a feeling of pressure in the stomach, bloating
- itching, rash, hives

#### Rare (may affect up to 1 in 1,000 people)

- decreased heart rate, increase in blood pressure, fainting, pathological condition of the blood.
- changes in appetite, tingling, tremor, respiratory depression, epileptiform convulsions
- hallucinations, confusion, somnolence, sleep disturbance and nightmares. Psychic side effects such as changes in mood (usually elation, occasionally dysphoria), changes in activity (usually suppression, occasionally increase) and changes in cognitive and sensorial ability (e.g. decision behaviour, perception disorders) which can vary from nature and intensity
- blurred vision
- flushing
- muscle weakness
- increase in liver enzyme values
- difficulty in passing urine and urinary retention
- symptoms of withdrawal reactions: agitation, anxiety, nervousness, insomnia, hyperkinesia, tremor and gastrointestinal symptoms

#### Not known (frequency cannot be estimated from the available data)

- decrease in blood sugar level

Worsening of asthma has been reported, though a causal relationship has not been established.

### **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 national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE TRAMADOL HYDROCHLORIDE

Keep this medicine out of the reach and sight of children.

Store below 25°C. Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the label and the carton after "EXP". The expiry date refers to the last day of that month.

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 Hydrochloride contains

- The active substance is tramadol hydrochloride. One tablets contains 50 mg tramadol hydrochloride.
- The other ingredients are lactose monohydrate (see also "Tramadol Hydrochloride contains lactose" under section 2), microcrystalline cellulose, carmellose sodium and magnesium stearate.

### What Tramadol Hydrochloride looks like and contents of the pack

It is a white, round oral tablet containing 50mg of tramadol hydrochloride. Each tablet has T printed on one face with a breakline on the reverse.

The tablets are packaged in blister strips made of PVC or aluminium foil and supplied in cartons of 10, 30, 60 and 100.

### Marketing Authorisation Holder and Manufacturer

Eurogenerics NV - Heizel, Esplanade b22 - 1020 Brussels - Belgium

### Manufacturer

[to be completed nationally]

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

UK: Tramadol Hydrochloride  
50 mg tablets  
BE: Tramadol EG 50 mg tabletten  
LU: Tramadol EG 50 mg  
comprimés

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