

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Zamadol® Capsules 50mg** tramadol hydrochloride

**This medicine contains tramadol hydrochloride, which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.**

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

#### **1. What Zamadol is and what it is used for**

The name of your medicine is **Zamadol® Capsules 50 mg** (referred to as Zamadol throughout this leaflet).

Zamadol contains tramadol hydrochloride which belongs to a group of medicines called opioids, which are ‘pain relievers’. Tramadol interrupts the pain messages being sent to your brain, and it also acts in your brain to stop pain messages from being felt. This means that Zamadol does not stop the pain from happening, but you will not be able to feel the pain as much.

This medicine has been prescribed for moderate to severe, a sudden or a long-standing pain (for example pain after an operation, or after an injury) in adults and adolescents aged 12 years and older.

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 it suddenly. Your doctor should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

#### **2. What you need to know before you take Zamadol**

##### **Do not take Zamadol if:**

- you are allergic to tramadol hydrochloride or to any of the other ingredients of this medicine (listed in section 6), resulting in a skin rash, swelling of face or difficulty in breathing.
- you are taking, or you have taken in the last two weeks, monoamine oxidase inhibitors (MAOIs) to treat your depression (see section 2, “Other medicines and Zamadol”)
- you are suffering from uncontrolled epilepsy
- you have drunk enough alcohol to make you feel woozy or drunk

- you have taken more than prescribed dose of your sleeping tablets, antipsychotics, anti-depressants (antipsychotics and antidepressants are medicines that affect mood and emotions) or other pain killers, which can slow down your breathing and reactions.

## **Warnings and precautions**

### 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 Zamadol 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 Zamadol 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 Zamadol, 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 Zamadol).

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 doctor 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.

### **Sleep-related breathing disorders**

Zamadol 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.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your doctor about your treatment.

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

Also, talk to your doctor or pharmacist before taking Zamadol, if:

- you have been taking Zamadol or any other medicine containing tramadol for a long time.
- you are addicted to morphine.
- you have severe problems with your liver or kidneys.
- you have recently had a head injury or have a very bad headache that makes you sick.
- you have ever had convulsions (fits) or you suffer from epilepsy.
- you have asthma or trouble breathing.
- you have recently felt confused, sleepy or faint, or you have fainted.
- you are going to have surgery requiring a general anaesthetic.
- you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Zamadol').

If any of the above applies to you, you must tell your doctor as they may decide to alter your treatment.

There is the rare possibility that Zamadol may cause convulsions (fits). The risk is increased if doses above the daily maximum are taken and if you are also taking anti-depressants or antipsychotics.

If you have a tendency to drug addiction or abuse, you should take Zamadol for short periods only. Please tell your doctor about this as they may want to monitor your pain control more closely.

You should not take this product for the treatment of withdrawal symptoms, if you are addicted to drugs.

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.

You should also contact your doctor if you have these symptoms; 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). Your doctor will decide if you need to take hormone supplement.

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').

### **Children and adolescents**

Zamadol should not be taken by children under 12 years of age.

#### 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 Zamadol**

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

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

- The pain relief effect of Zamadol may be weakened and/or shortened if you also take medicines containing:
  - Carbamazepine (used to treat epilepsy)
  - Buprenorphine, nalbuphine, or pentazocine (pain killers)
  - Ondansetron (prevents nausea)
- The risk of side effects increases if you are taking certain antidepressants. Zamadol may interact with these medicines and you may experience serotonin syndrome (see section 4 ‘Possible side effects’). 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 Zamadol at the same time. Your doctor will tell you whether Zamadol is suitable for you.
- Medicines used to treat epilepsy may very rarely cause convulsions (fits), but if you are also taking Zamadol the possibility of having a convulsion is more likely. You must ask your doctor about this.
- Medicines that act on the nervous system such as hypnotics, tranquillisers, sleeping pills and pain killers may make you feel drowsier or faint when taken with Zamadol.
- Anticoagulants to thin your blood such as warfarin. The effectiveness of the medicines may be altered if you are also taking Zamadol.
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).

### **Zamadol with food, drink and alcohol**

Zamadol should be taken with some water, with or without a meal. Avoid drinking alcohol while taking this medicine.

### **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. Please contact your doctor if you become pregnant during your treatment.

### **Pregnancy**

Do not take Zamadol if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Zamadol during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

### **Breast-feeding**

Do not take Zamadol while you are breastfeeding as tramadol passes into breast milk and will affect your baby.

### **Driving and using machines**

Even when taken according to instructions, Zamadol may impair the reactions of drivers, machine operators and workers without a safe hold. This effect may be potentiated by alcohol, at the beginning of treatment, when switching the drug, and on concomitant use of other CNS-depressants or anti-histamines. If patients are affected they should be warned not to drive or operate 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.

### 3. How to take Zamadol

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The usual dose is 1 or 2 capsules every 4 to 6 hours.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Zamadol, 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).

**Important: Your doctor will choose the dose that is right for you or your child. 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 number of capsules to be taken will be shown clearly on the label that your pharmacist puts on the medicine. If it is not, or you are not sure, ask your doctor or pharmacist.**

To ensure safety for children, Zamadol capsules are packed in a child-resistant foil. The child-resistant sealing foil is stronger, making it more difficult to push the capsules through.

To avoid damaging the capsules when the capsule is pushed through the child-resistant sealing foil, pre-perforate the foil and then push the capsule out of the blister.

Swallow the capsules whole with some water without chewing.

If you have difficulty in swallowing, you may open the capsules. You must open them very carefully by pulling and twisting each end over a spoon so that all the pellets stay in the spoon. Do not chew. Swallow all the pellets with water.

#### **Dosage for adults and adolescents aged 12 years and older is:**

One or two Zamadol (equivalent to 50–100 mg tramadol hydrochloride). Depending on the pain, the effects lasts for about 4–8 hours.

Your doctor may increase this dose up to 150–200 mg twice daily according to your needs.

The maximum dose is usually 400 mg daily.

Your prescribed daily dose will depend on the severity of your pain.

#### **Use in children:**

Zamadol should not be taken by children under 12 years of age.

#### **Use in elderly patients:**

In elderly patients (above 75 years of age) the excretion of tramadol may be delayed. If this applies to you, your doctor may recommend prolonging the dosage interval.

#### **Use in patients with severe liver or kidney disease (insufficiency)/dialysis patients:**

Patients with severe liver and/or kidney insufficiency should not take Zamadol.

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

#### **Method of administration:**

Ask your doctor or pharmacist if:

- you are not sure how many tablets to take or when to take them
- you think that the effect is too strong or too weak

Swallow the capsules whole with water without chewing.

If you have difficulty in swallowing, your doctor may advise you to open the capsules. The capsules should be opened very carefully by pulling and twisting each end. The capsule should be opened over a spoon so that all the pellets stay in the spoon. The pellets should then be swallowed, take a sip of water afterwards to make sure that you have swallowed all the pellets. Remember that the pellets should not be chewed.

**If you take more Zamadol than you should** If you accidentally take more tablets than your prescribed dose, tell your doctor or pharmacist immediately and if necessary contact your nearest hospital casualty department. Remember to take the pack and any remaining capsules with you.

#### **If you forget to take Zamadol**

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

#### **If you stop taking Zamadol**

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your doctor 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.

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

Ask your doctor or pharmacist if:

- you are not sure how many capsules to take or when to take them.
- you think that the effect is too strong or too weak.

There is a risk that you may become addicted to or dependent on these tablets (a need to keep taking the medicines). If you take these for a long time you can become used to the effects and you may need to take higher doses to control your pain.

## **4. Possible side effects**

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

The most serious side effects which may occur include allergic reaction (difficulty in breathing, wheezing and swelling of the face or throat), anaphylactic reaction (an extreme allergic reaction resulting in difficulty breathing, changes in heart rate, faintness, collapse or unconsciousness due to a drop in blood pressure) or convulsions (fits). If you have any of these symptoms you must stop taking Zamadol immediately and seek medical advice.

### **Other side effects**

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

- dizziness
- vomiting and nausea (being and feeling sick)

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

- headache
- drowsiness, sleepiness (fatigue)
- constipation, dry mouth
- sweating

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

- rapid heart beat, palpitation, sudden drops in blood pressure. These adverse effects may occur especially on intravenous administration and in patients who are physically stressed
- itching, skin rash
- retching, feeling bloated or full

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

- appetite changes
- psychic effects including: changes in mood, activity, behaviour and perception, hallucinations, confusion, restlessness, sleep disturbances and nightmares
- convulsions (fits)
- tingling sensation and trembling
- slow heart beat, increase in blood pressure
- muscle weakness
- difficulty or inability in passing urine
- blurred vision
- flushing

**Very rare (may affect up to 1 in 10,000 people)**

- vertigo (feeling of dizziness or “spinning”)
- asthma and breathing difficulties
- elevated liver enzymes

**Not known: frequency cannot be estimated from the available data**

- low blood sugar level
- low blood sodium level which can cause tiredness and confusion, muscle twitching, fits and coma’
- 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 Zamadol’).
- Dependence and addiction (see section ‘How do I know if I am addicted?’)

**Drug Withdrawal**

When you stop taking Zamadol, 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 Zamadol, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your doctor
- 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 doctor.

**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](http://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 Zamadol**

- Do not store above 30°C.
- 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. The expiry date refers to the last day of that month.
- Keep your capsules in the original package.
- 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 Zamadol Capsules 50 mg contains:**

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

The other ingredients are: calcium hydrogen phosphate, anhydrous, magnesium stearate, colloidal anhydrous silica, gelatin, titanium dioxide (E171), shellac, Iron oxide, black (E172), propylene glycol, ammonium hydroxide.

### **What Zamadol Capsules 50 mg look like and contents of the pack**

The 50 mg Capsules are white in colour with black T 50 printing.

All the capsules are packaged in blister strips of 10 capsules, with 1, 2, 3, 5, 6 or 10 blister strips in each carton. These presentations are not available in all countries.

### **Marketing Authorisation Holder:**

#### **Mylan Products Ltd.**

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### **Manufacturer:**

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