

Package Leaflet: Information for the user

Zamadol® 50 mg Melt

tramadol hydrochloride

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your 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 Melt is and what it is used for
2. What you need to know before you take Zamadol Melt
3. How to take Zamadol Melt
4. Possible side effects
5. How to store Zamadol Melt
6. Contents of the pack and other information

1. What Zamadol Melt is and what it is used for

The name of your medicine is **Zamadol Melt** (referred to as a Zamadol Melt throughout this leaflet). "Melt" means that these tablets will dissolve on your tongue.

Zamadol Melt belongs to a group of medicines called analgesics, commonly known as pain killers or pain relievers. The active substance, tramadol hydrochloride, 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 Melt does not stop the pain from happening, but you will not be able to feel the pain as much. Zamadol Melt is used to relieve moderate to severe a sudden or a long-standing pain (for example pain after an operation, or after an injury).

2. What you need to know before you take Zamadol Melt

Do not take Zamadol Melt:

- if you are allergic (hypersensitive) to tramadol hydrochloride or to any of the other ingredients resulting in a skin rash, swelling in face or difficulty in breathing (ingredients are listed in section 6)
- if you are taking, or you have taken in the last two weeks, monoamine oxidase inhibitors (MAOIs), these are medicines to treat depression
- if you are suffering from uncontrolled epilepsy
- if you have drunk enough alcohol to make you feel woozy or drunk
- if you have taken more than the prescribed dose of your sleeping tablets or other pain killers, which can slow down your breathing and reactions. (See section taking other medicines for details)
- if you are breast-feeding
- if you are under 12 years of age

Warnings and precautions

Talk to your doctor or pharmacist before taking Zamadol Melt if:

- You should not take this product for the treatment of withdrawal symptoms caused by opiates (morphine-like medicines).
- You have a head injury or breathing difficulties.
- You suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Zamadol Melt').

There is rare possibility that Zamadol Melt 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.

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

Zamadol Melt 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 if you experience any of the following symptoms while taking Zamadol Melt:

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.

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 Melt 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 Melt 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 Melt, 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 Melt).

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').

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

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 Zamadol Melt

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

Do not take Zamadol Melt 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 Melt 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)

Your doctor will tell you whether you take Zamadol Melt, and what dose.

Concomitant use of Zamadol Melt 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 Zamadol Melt 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.

The risk of side effects increases if you are taking gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).

The risk of side effects increases if you are taking certain antidepressants. Zamadol Melt may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects'). **You must tell your doctor** if you are taking any of these medicines.

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 Melt at the same time. Your doctor will tell you whether Zamadol Melt is suitable for you.

- Medicines used to treat epilepsy may very rarely cause convulsions (fits), but if you are also taking Zamadol Melt 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 Melt.
- Anticoagulants to thin your blood such as warfarin. The effectiveness of the medicines may be altered if you also taking Zamadol Melt.

Tell your doctor or dentist if you are taking any of these medicines.

Zamadol Melt with food, drink and alcohol

You can take Tramadol with or without meal. It is better not to drink alcohol with 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

You should not take Zamadol Melt during pregnancy, since the active substance tramadol hydrochloride passes the placenta, and its safety during pregnancy has not been established. If

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you suffer from severe pain, you should consult your treating physician, who has to decide, whether you can take single doses.

Breast-feeding

Tramadol is excreted into breast milk. For this reason, you should not take Zamadol Melt more than once during breast-feeding, or alternatively, if you take Zamadol Melt more than once, you should stop breast-feeding.

Driving and using machines

Zamadol Melt may cause drowsiness, particularly if taken with alcohol, anti-histamines and other medicines that may cause drowsiness. Do not drive or operate heavy machinery unless you know how Zamadol Melt affects you.

Zamadol Melt contains aspartame and glucose

This medicine contains 20 mg aspartame in each tablet. Aspartame contains a source of phenylalanine which may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

The mint rootbeer flavouring contains maltodextrine (glucose). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Zamadol Melt

Always take Zamadol Melt exactly as your doctor has told you. You should 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 Zamadol Melt, 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 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.

Dosage for adults and adolescents from 12 years of age:

The usual dose is 1 or 2 tablets every 4 to 6 hours.

The **maximum dose** is usually 400mg daily (8 tablets).

Use in children:

Zamadol Melt 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.

Severe liver or kidney disease (insufficiency)/dialysis patients:

Patients with severe liver and/or kidney insufficiency should not take Zamadol Melt. If in your case the problem 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

Do not swallow or chew Zamadol Melt. These tablets should be sucked, as they will dissolve on your tongue. If necessary you may dissolve each tablet in half a glass of water.

If you take more Zamadol Melt 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 tablets with you.

If you forget to take Zamadol Melt

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

If you stop taking Zamadol Melt

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).

Withdrawal symptoms including: agitation, anxiety, nervousness, difficulty sleeping, restlessness, trembling and gastro-intestinal problems (see section 4 'Possible side effects').

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

4. Possible side effects

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

Please stop taking this medicine and contact your doctor as soon as possible if you experience any of the following rare reaction:

- allergic reaction such as difficulty in breathing, wheezing, swelling of the face or throat.
- anaphylactic reaction (an extreme allergic reaction)

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 behavior 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
- dependency

Very rare: may affect up to 1 in 10,000 people

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

Not known: frequency cannot be estimated from the available data

- decrease in blood sugar level
- low blood levels of sodium 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 Melt').

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Yellow Card Scheme at:

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 Melt

- 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 Zamadol Melt after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store in the original package.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Zamadol Melt contains:

The active substance in Zamadol Melt is tramadol hydrochloride. Each orodispersible tablet contains 50 mg tramadol hydrochloride. It also contains other ingredients including: ethylcellulose, copovidone, silicon dioxide, mannitol (E421), crospovidone, aspartame (E951), mint rootbeer flavouring, magnesium stearate.

What Zamadol Melt look like and contents of the pack

The 50 mg tablets are round white in colour with printing 'T' on one and '50' on the other side with a characteristic mint flavour.

Pack sizes: 10, 20, 28, 30, 40, 50, 56, 60 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Mylan Products Ltd., Station Close, Potters Bar, Hertfordshire, EN6 1TL, UK

Manufacturer:

MEDA Pharma GmbH & Co KG., Benzstraße 1, D-61352 Bad Homburg, Germany

Or

Mylan Hungary Kft./Mylan Hungary Ltd., Mylan utca 1, Komárom 2900 Hungary.

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