

PATIENT INFORMATION LEAFLET

Zamadol® Melt 50mg Tablets
(Tramadol Hydrochloride)

Please read this leaflet carefully before you start taking this medicine. You should keep this leaflet as it provides the information you need to know about your medicine. If you have any further questions or are not sure about your medication, please ask your doctor or pharmacist.

Remember, this medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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**Zamadol® Melt 50mg Tablets**
(Tramadol Hydrochloride)

The active substance in **Zamadol Melt** is tramadol hydrochloride. Each tablet contains 50mg tramadol hydrochloride. It also contains other ingredients including: ethylcellulose N7, copovidone, silicon dioxide, mannitol (E421), crospovidone, aspartame (E951), mint rootbeer flavouring, magnesium stearate.

The marketing authorisation holder for **Zamadol Melt** is: **MEDA Pharmaceuticals Ltd**, Beach Drive, Cambridge Research Park, Waterbeach, Cambridge, CB5 9PD, UK.

The manufacturer of **Zamadol Melt** is: **Ethypharm Industries**, Z.I. de Saint-Arnoult, 28170 Châteauneuf-en-Thymerais, FRANCE.

1. WHAT ZAMADOL MELT IS AND WHAT IT IS USED FOR

The name of your medicine is **Zamadol Melt** (common name tramadol hydrochloride). 'Melt' means that these tablets will dissolve on your tongue. The tablets are white in colour and packaged in blister strips of 10 tablets with 1, 6 or 10 blister strips in each carton.

Zamadol Melt is an analgesic (pain killer or pain reliever). The active ingredient of **Zamadol Melt** is tramadol; it interrupts the pain messages being sent to your brain, and it also reacts in your brain to stop pain messages from being felt. This means that tramadol 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 sudden or long-standing pain, either when the pain occurs or to prevent pain from occurring. The type of pain may be moderate or severe and it can be any type of pain, for example pain after an operation, or after an injury, or the pain of arthritis. Pain relief is normally felt within 30 minutes and lasts for about 6 hours.

2. BEFORE YOU TAKE ZAMADOL MELT

DO NOT take **Zamadol Melt** if:

- You are a child under 12 years of age.
- You have ever experienced an allergic reaction to tramadol hydrochloride or any of the ingredients in this medicine. Allergic reactions to tramadol could include skin rash, swelling of the face, wheezing or difficulty in breathing.
- You are pregnant or breastfeeding.
- You are taking, or have taken in the last two weeks, monoamine oxidase inhibitors (MAOIs) - these are medicines to treat depression.
- You are suffering from uncontrolled epilepsy.
- You have taken enough alcohol to make you feel even slightly drunk or you have taken several sleeping pills, other pain killers or any other medicines which slow down your thinking or breathing rate.
- You are taking strong pain killers containing nalbuphine, buprenorphine, pentazocine or carbamazepine.

Take special care with Zamadol Melt:

If the answer to any of the following questions is 'yes', you must tell your doctor - he may decide to alter your treatment:

- Have you been taking **Zamadol** or any other tramadol containing medicine for a long time?
- Are you addicted to morphine or have a tendency to drug abuse?
- Have you had an allergic reaction to any morphine-like medicines?
- Do you have severe problems with your liver or kidneys? (If you have kidney or liver problems or are over 75 years, you may need a lower dose of **Zamadol Melt** or a longer interval between doses).
- Have you recently had a head injury or do you have a very bad headache that makes you sick?
- Have you ever had convulsions (fits), or do you suffer from epilepsy?
- Do you have asthma or trouble breathing?
- Are you taking any antidepressants, antipsychotics (drugs for schizophrenia) or anticonvulsants (drugs for epilepsy), tranquillisers (drugs to treat anxiety) or anti-histamines that cause drowsiness?

Taking Zamadol Melt with food and drink:

Zamadol Melt is not known to react badly with food or soft drinks. It is better not to drink alcohol with this medicine. You should not take **Zamadol Melt** even if you are feeling slightly drunk.

Driving and using machines:

Zamadol Melt may cause drowsiness. If this occurs you should not drive or operate tools or machines.

Important information about some of the ingredients:

The ingredient aspartame contains a source of phenylalanine which may be harmful to people with phenylketonuria.



Taking other medicines with Zamadol Melt:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

If you are taking certain types of antidepressant, such as tricyclic antidepressants (TCAs) or selective serotonin re-uptake inhibitors (SSRIs), or you are being treated with antipsychotic or anticonvulsant medicines there is a risk that Zamadol Melt may increase the possibility of a convulsion occurring. You must ask your doctor about this.

If you are taking carbamazepine for treatment of epilepsy, coumarin anticoagulants (blood thinning medicines) such as warfarin, or monoamine oxidase inhibitors or lithium for treatment of depression, you must tell your doctor.

Zamadol Melt may cause drowsiness and this effect may be increased by antidepressant medication, or other medicines which slow down your nervous system (making you feel faint). These include sleeping pills, tranquillisers, anti-histamines that make you drowsy, antipsychotics, other pain killers or a general anaesthetic. Tell your doctor or dentist if you are taking any of these medicines. If you feel drowsy, do not drive or operate machinery.

3. HOW TO TAKE ZAMADOL MELT

Always take Zamadol Melt exactly as instructed by your doctor. If you are unsure please check with your doctor or pharmacist.

The usual dose is 1 or 2 tablets every 4 to 6 hours. The number of tablets you take and how often will depend on the type of pain you have and how strong it is. Normally you should not take more than 8 tablets per day (400 mg). Check the label for how many tablets to take and how often to take them. If you are not sure how many tablets to take, ask your doctor or pharmacist.

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

If you have chronic pain (long-lasting pain), you should check regularly with your doctor that it is appropriate for you to continue taking tramadol.

If you take more Zamadol Melt than you should:

If you ever take too many tablets or if a child accidentally takes Zamadol Melt, contact your nearest hospital casualty department or tell your doctor immediately.

If you forget to take Zamadol Melt:

If you forget to take your medicine, take it as soon as you remember. Then take the next dose 6 hours later, but DO NOT TAKE MORE THAN ONE DOSE AT THE SAME TIME.

If you see a different doctor, or have to go to hospital:

If you see any other doctor or have to go to hospital for any reason, you must tell them about the Zamadol Melt and any other medication you are taking.

4. POSSIBLE SIDE EFFECTS

Like many other medicines, Zamadol Melt may have side effects. You may not have any of these side effects or you may have some of them. These side effects may include being sick or feeling sick, sweating, dry mouth, drowsiness, fatigue and tiredness, dizziness (especially after standing up suddenly from a sitting down position), palpitations, headache, constipation or irritation of the stomach (feeling of bloatedness).

Zamadol Melt may (rarely) also cause dependence (addiction), blurred vision, tingling sensations, hallucinations, nightmares and sleep disturbances, confusion, changes in mood such as feelings of sadness or nervousness, fits (convulsions), tremor, an increase or fall in blood pressure, difficulty passing urine and changes in appetite. Rarely withdrawal symptoms may be experienced when your treatment is stopped. If this occurs you may feel agitated, anxious, nervous or shaky, and you may have difficulty in sleeping. These effects will usually disappear within a few days.

Very rarely you may experience vertigo, flushing, worsening of asthma, difficulty in breathing or minor changes in liver function.

Sometimes an allergic reaction may occur. Allergic reactions to Zamadol may include itching or a skin rash. In rare cases, an allergic reaction to Zamadol Melt could make your asthma worse if you already have asthma, it could make you feel as though breathing is difficult, or it may cause angioneurotic oedema (a swelling of your face and lips). If you experience any of these allergic reactions, please stop taking the tablets immediately and contact your doctor.

If you suffer from any of the above mentioned effects, feel unwell, or have any other unusual discomfort you do not understand, please tell your doctor or pharmacist as soon as possible.

5. STORING ZAMADOL MELT

Keep your medicine out of the reach and sight of children. Your tablets could harm them. Store in the original package.

Do not use your tablets after the expiry date stated on the box, even if there are some left. Ask your doctor to replace them with a new prescription and take any unused tablets back to the pharmacist.

If your doctor tells you to stop taking your tablets, please take them back to the pharmacist.

6. FURTHER INFORMATION

For further information please contact the Marketing Authorisation Holder.

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