

Package leaflet: Information for the patient

Zamadol® 24hr 150 mg, 200 mg, 300 mg and 400 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 *Zamadol 24hr* tablets are and what they are used for
2. What you need to know before you take *Zamadol 24hr* tablets
3. How to take *Zamadol 24hr* tablets
4. Possible side effects
5. How to store *Zamadol 24hr* tablets
6. Contents of the pack and other information

1. What *Zamadol 24hr* tablets are and what they are used for

These tablets have been prescribed for you by your doctor to relieve moderate to severe pain over a period of 24 hours. They contain the active ingredient tramadol which is a strong analgesic ('painkiller') which belongs to a group of medicines called opioids. These tablets are only for use in adults and adolescents over 12 years of age.

2. What you need to know before you take *Zamadol 24hr* tablets

Do not take *Zamadol 24hr* tablets:

- if you are allergic to tramadol or any of the other ingredients of these tablets (listed in section 6);
- if you have drunk too much alcohol, or taken more than the recommended dose of sleeping tablets, painkillers or psychotropic medicines (used to treat psychiatric or mental disorders);
- if you are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranlylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or if you have taken this type of medicine in the last two weeks;
- to treat withdrawal symptoms that may occur when you stop taking another strong painkiller;

Warnings and precautions

Talk to your doctor or pharmacist before taking these tablets if you:

- are or have ever been addicted to alcohol or drugs;
- suffer from, or have ever suffered from epilepsy, seizures, fits or convulsions;
- have a severe headache or feel sick due to a head injury or increased pressure in your skull (for instance due to brain disease). This is because the tablets may make symptoms worse

- or hide the extent of a head injury;
- have severe liver or kidney problems;
- are suffering from shock (this may make you suddenly feel very light-headed, faint, cold or clammy and look pale);
- have a condition where you breathe more slowly and weakly than expected (respiratory depression).

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.

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 24hr* tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take

any other medicines. If you take these tablets with some other medicines, the effect of these tablets or the other medicine may be changed.

These tablets must not be used together with a monoamine oxidase inhibitor, or if you have taken this type of medicine in the last two weeks (see section 2 'Do not take...').

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 24hr* tablets at the same time. Your doctor will tell you whether *Zamadol 24hr* tablets are suitable for you.
- if you are taking certain antidepressants. *Zamadol 24hr* 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.

Tell your doctor or pharmacist if you are taking:

- medicines to help you sleep (for example tranquillisers, hypnotics or sedatives);
- carbamazepine to treat seizures, fits or

- convulsions and certain pain conditions;
- medicines to treat depression;
- medicines to treat psychiatric or mental disorders;
- ritonavir to treat HIV;
- digoxin to treat heart failure or an irregular heart beat;
- other strong analgesics or 'painkillers' (such as buprenorphine, nalbuphine and pentazocine);
- certain morphine-like medicines used for example, to prevent or treat coughing, or to treat the symptoms of withdrawal;
- medicines known as barbiturates to either treat fits or to help you sleep;
- medicines known as benzodiazepines to treat anxiety or to help you sleep;
- certain medicines to prevent your blood clotting or to help thin your blood (known as coumarin anticoagulants, for example warfarin);
- ondansetron to stop you feeling or being sick.

Taking *Zamadol 24hr* tablets and alcohol

Please ask your doctor or pharmacist for advice if you intend to drink alcohol while you are being treated with these tablets.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking these tablets.

Pregnancy

Do not take these tablets if you are pregnant. Depending on the dose and duration of treatment with tramadol, slow and shallow breathing (respiratory depression) or withdrawal symptoms may occur in the newborn infant.

Breastfeeding

Tramadol is excreted into breast milk. For this reason, you should not take *Zamadol 24hr* tablets more than once during breastfeeding, or alternatively, if you take *Zamadol 24hr* tablets more than once, you should stop breastfeeding.

Driving and using machines

These tablets may cause a number of side effects such as drowsiness, blurred vision and dizziness which could affect your ability to drive or use machinery (see section 4 for a full list of side effects). These are usually most noticeable when you first start taking the tablets, or when changing to a higher dose. If you are affected you should not drive or use machinery.

This 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 while you have this medicine in your body over a specified limit unless you have a defence (called the 'statutory defence').

- This defence applies when:
 - o The medicine has been prescribed to treat a medical or dental problem; and
 - o You have taken it accordingly to the instructions given by the prescriber and in the information provided with the medicine.
- Please note that it is still an offence to drive if you are unfit because of the medicine (i.e. your ability to drive is being affected).

Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here: <https://www.gov.uk/drug-driving-law>.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Zamadol 24hr contain lactose

These tablets contain lactose which is a form of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

3. How to take *Zamadol 24hr* tablets

Always take these tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The label on your medicine will tell you how many tablets to take and how often.

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.

Adults and adolescents over 12 years of age
The usual starting dose is one 150 mg tablet once a day. However, your doctor will prescribe the dose required to treat your pain. Do not exceed the dose recommended by your doctor. If you find that you are still in pain whilst taking these tablets discuss this with your doctor. You should not normally take more than 400 mg a day.

Swallow your tablets whole with water. **Do not crush, dissolve or chew them. *Zamadol 24hr* tablets are designed to work properly over 24 hours when swallowed whole. If a tablet is broken, crushed, dissolved or chewed, the entire 24-hour dose may be absorbed rapidly into your body. This can be dangerous, causing serious problems such as an overdose, which may be fatal.**

You should take your tablets at the same time every day. For instance, if you take a tablet at 8 o'clock in the morning, you should take your next tablet at 8 o'clock the next morning.

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 *Zamadol 24hr* tablets. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

Children under 12 years of age
Children under 12 years of age should not take the tablets.

If you take more *Zamadol 24hr* tablets than you should or if someone accidentally swallows your tablets
Call your doctor or local hospital straight away. People who have taken an overdose may feel very sleepy, sick or dizzy. They may have seizures, fits or convulsions. They may also have breathing difficulties leading to unconsciousness or even death and may need emergency treatment in hospital. When seeking medical attention make sure that you take this leaflet and any remaining tablets with you.

If you forget to take *Zamadol 24hr* tablets
If you remember within 10 hours of the time your tablet was due, take your tablet straight away. Take your next tablet at

your normal time. If you are more than 10 hours late, please call your doctor for advice. Do not take a double dose to make up for a forgotten tablet.

If you stop taking *Zamadol 24hr* tablets
You should not suddenly stop taking your tablets unless your doctor tells you to. If you want to stop taking your tablets, discuss this with your doctor first, particularly if you have been taking them 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 such as agitation, anxiety, nervousness, difficulty in sleeping, being unusually overactive, shaking or gastrointestinal disorders e.g. upset stomach, may occur if you suddenly stop taking these tablets.

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

4. Possible side effects

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

All medicines can cause allergic reactions, although serious allergic

reactions are rare. Tell your doctor immediately if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body.

The most serious side effect is a condition where you breathe more slowly or weakly than expected (respiratory depression).

As with all strong painkillers, there is a risk that you may become addicted or reliant on these tablets.

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

- Feeling sick (this should normally wear off after a few days however your doctor can prescribe an anti-sickness medicine if it continues to be a problem).
- Dizziness.

Common (may affect up to 1 in 10 people)

- Drowsiness (this is most likely when you start taking your tablets or when your dose is increased, but it should wear off after a few days.)
- Dry mouth.
- Sweating.
- Vomiting (being sick).

Uncommon (may affect up to 1 in 100 people)

- Headache.
- Fast heart beat, palpitations or severe heart problems.
- A feeling of 'faintness' especially

- on standing up, low blood pressure.
- Constipation.
- Abdominal pain or discomfort.
- Rash, hives (nettle rash) or itchy skin.

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

- Tingling or numbness.
- Blurred vision.
- Hallucinations.
- Nightmares.
- Mood changes, unpleasant or uncomfortable moods or a feeling of extreme happiness.
- Changes in activity levels.
- Confusion
- Problems with recognition, changes in thinking, memory and behaviour.
- Seizures, fits or convulsions.
- High blood pressure.
- Shortness of breath, difficulty in breathing or wheezing.
- Worsening of asthma.
- Loss of appetite.
- Diarrhoea.
- Pain or difficulty in passing urine.
- Muscle weakness.
- Flushing of the skin.
- Slow heart beat.

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

- Withdrawal symptoms when you stop taking these tablets such as agitation, anxiety, nervousness,

overactivity, shaking (tremor), difficulty in sleeping, upset stomach.

- A worsening in liver function tests (seen in a blood test).

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

- A feeling of unusual weakness.
- Decrease in the blood sugar level.

You may see the remains of the tablets in your faeces. This should not affect how the tablets work.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any 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 24hr* tablets

Keep these tablets out of the sight and reach of children.

Do not take these tablets after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Do not store your tablets above 30°C.

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 24hr* tablets contain

The active ingredient is tramadol hydrochloride. Each tablet contains 150 mg, 200 mg, 300 mg or 400 mg of tramadol hydrochloride.

The other ingredients are:

- Hydrogenated vegetable oil
- Talc
- Magnesium stearate
- Lactose monohydrate
- Macrogol
- Hypromellose (E464)
- Titanium dioxide (E171)

What *Zamadol 24hr* tablets look like and the contents of the pack

They are white, film-coated, oval shaped tablets marked T followed by the strength (e.g. 150, 200, 300 or 400). The 150 mg strength tablets are approximately 13 mm in length, the 200 mg strength tablets are approximately 15 mm in length, the 300 mg strength tablets are

approximately 17 mm in length and the 400 mg strength tablets are approximately 19 mm in length.

In each box there are 28 tablets.

Marketing Authorisation Holder and Manufacturer

The tablets are made by VEMEDIA Manufacturing, B.V., Verrijn Stuartweg 60, 1112 AX Diemen, The Netherlands, for the marketing authorisation holder Napp Pharmaceuticals Limited, Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK.

Zamadol 24hr 150 mg, 200 mg, 300 mg and 400 mg tablets are supplied by Meda Pharmaceuticals Ltd, Skyway House, Parsonage Road, Takeley, Bishop's Stortford, CM22 6PU, UK.

Is this leaflet hard to see or read?

Please contact Meda Pharmaceuticals Ltd at the address above.

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<p>Klantnaam : Vemedia Manufacturing B.V.</p> <p>Artikelnummer : 734651 11/17</p> <p>Ordernummer :</p> <p>Versie drukproef : 6</p> <p>F.090.1111</p>	<p>Gebruikte kleuren</p> <p> pms 280</p>	<p>Deze standproef is niet maatgevend voor drukkleur, papierkwaliteit en afmetingen. De productie start pas na ontvangst van uw akkoord. (*bij manuaalfilm is afmeting wel maatgevend)</p> <p><input type="checkbox"/> Proef Akkoord <input type="checkbox"/> Revisie Proef</p>
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