PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

ZYTRAM® 150 mg prolonged-release tablets

ZYTRAM® 200 mg prolonged-release tablets

ZYTRAM® 300 mg prolonged-release tablets

ZYTRAM® 400 mg prolonged-release tablets

Tramadol hydrochloride

Contains lactose

Read all of this leaflet carefully before you start using ZYTRAM®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ZYTRAM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. What ZYTRAM is and what it is 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 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 ZYTRAM

Do not take ZYTRAM:

- if you are hypersensitive (allergic) to tramadol or any of the other ingredients of ZYTRAM (listed in section 6);
- if you are younger than 12 years of age;
- if you are younger than 18 years of age following tonsillectomy and/or adenoidectomy;
- 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 tranylcypromine, 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;
- if you have epilepsy;
- if you suffer from increased pressure in the brain (possibly after a head injury or brain disease);
- if you have difficulty in breathing;
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Tell your doctor or health care provider 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;
- suffer from lactose intolerance;
- 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.

You may experience low levels of sodium in the blood (hyponatraemia) while taking this medicine. Symptoms of low blood sodium may include nausea and vomiting, headaches, feeling confused, feeling very tired, feeling restless, feeling irritable, muscle weakness, spasms or cramps and seizures. Elderly patients and patients taking other medicines that lower sodium in the blood are most at risk for this side effect. If you get any of these symptoms while taking ZYTRAM, consult with your doctor immediately.

ZYTRAM can lead to psychological and physical dependence or addiction in some people, especially with long term use. The dose needed to achieve the desired effect may increase with time. ZYTRAM should be used with caution, and only for short periods under strict medical supervision, in patients who are addicted to other opioid painkillers.

Please also inform your doctor if any of these problems occur during ZYTRAM treatment or if they applied to you in the past. 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 ZYTRAM

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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 ZYTRAM at the same time. Your doctor will tell you whether ZYTRAM is suitable for you.
- if you are taking certain antidepressants ZYTRAM 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.

- if you are taking warfarin (medicine for inhibiting blood clotting) together with ZYTRAM. The effect of warfarin on blood clotting may be increased and bleeding may occur.

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.

ZYTRAM with alcohol, food and drink

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

Do not drink alcohol during treatment with ZYTRAM as the effects of ZYTRAM and alcohol may intensify each other. Food does not influence the effect of ZYTRAM.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy

Do not take ZYTRAM 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 ZYTRAM during breastfeeding.

Babies born to mothers who have used ZYTRAM in pregnancy can suffer withdrawal symptoms which may include high-pitched crying, irritability and restlessness, shaking (tremor), feeding difficulties and sweating.

Driving and using machines

ZYTRAM 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.

ZYTRAM contains 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 ZYTRAM

Do not share medicines prescribed for you with any other person.

Always take ZYTRAM exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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.

Your doctor will tell you how long your treatment with ZYTRAM will last. If you have the impression that the effect of ZYTRAM is too strong or too weak, tell your doctor or pharmacist.

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. You may take tablets on an empty stomach or with meals.

ZYTRAM is 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 ZYTRAM. 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 ZYTRAM than you should

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 ZYTRAM

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 ZYTRAM

You should not suddenly stop taking ZYTRAM unless your doctor tells you to. If you want to stop taking ZYTRAM discuss this with your doctor first, particularly if you have been taking ZYTRAM 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.

4. Possible side effects

ZYTRAM can have side effects.

Not all side effects reported for ZYTRAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZYTRAM please consult your health care provider for advice.

If any of the following happens, stop taking ZYTRAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching.

Tell your doctor immediately or got to the casualty department at your nearest hospital if you notice any of the following:

- difficulty breathing.

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

Frequent side effects

- nausea (feeling sick),
- vomiting,
- dizziness,
- drowsiness,
- dry mouth,
- sweating.

Less frequent side effects:

- headache,
- fast heartbeat,
- irregular heartbeat (palpitations),
- slow heartbeat,
- a feeling of ‘faintness’ especially on standing up,
- low or high blood pressure,

- constipation,
- abdominal pain or discomfort,
- rash, hives or itchy skin,
- tingling or numbness,
- blurred vision,
- hallucinations,
- nightmares,
- mood changes, including feeling depressed or feeling very happy,
- changes in activity levels,
- confusion,
- problems with recognition and understanding,
- seizures, fits or convulsions,
- 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,
- 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),
- decrease in the blood sugar level,
- a feeling of unusual weakness,
- withdrawal symptoms in babies born to mothers who have used tramadol in pregnancy (see section 2 ‘Pregnancy, breastfeeding and fertility’).

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 side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or you can report directly to the company at ZADrugsafety@mundipharma.co.za.

By reporting side effects, you can help provide more information on the safety of ZYTRAM.

5. How to store ZYTRAM

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

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, hypromellose (E464), lactose monohydrate, magnesium stearate, macrogol, talc, titanium dioxide (E171)

What ZYTRAM looks like and the contents of the pack

ZYTRAM tablets 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.

Holder of Certificate of Registration

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