

ZALDIAR

1. What this product is and what it is used for

ZALDIAR is a combination of two analgesics, tramadol and paracetamol, which act together to relieve your pain.

ZALDIAR is intended for use in the treatment of moderate to severe pain when your doctor recommends that a combination of tramadol and paracetamol is needed.

ZALDIAR should only be taken by adults and adolescents over 12 years.

2. What you need to know before you use this product

Do not take ZALDIAR

- if you have had an allergic reaction (for instance skin rash, swelling of the face, wheezing or difficulty breathing) after taking tramadol or paracetamol or any of the other ingredients in ZALDIAR;
- in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions);
- if you are also taking MAO inhibitors (certain medicines used for treatment of depression or Parkinson's disease) or have taken them in the last 14 days before treatment with ZALDIAR;
- if you suffer from a severe liver disorder;
- if you have epilepsy that is not adequately controlled on your current medicine.

Take special care with ZALDIAR if you

- take other medicines containing paracetamol or tramadol;
- have liver problems or liver disease or if you notice your eyes and skin turning yellow. This may suggest jaundice or problems with your bile ducts.
- have kidney problems;
- have severe difficulties in breathing for example asthma or severe lung problems;
- have epilepsy or have already experienced fits or seizures;
- have recently suffered from a head injury, shock or severe headaches associated with vomiting;
- are dependent on any medicines including those used to relieve pain, for example morphine;
- take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine;
- are going to have an anaesthetic. Tell your doctor or dentist that you are taking ZALDIAR.

If any of the above-mentioned points applied to you in the past or applies to you while you are taking ZALDIAR, please make sure your doctor knows. He/she can then decide whether you should continue to use this medicine.

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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Important: This medicine contains paracetamol and tramadol. Tell your doctor if you are taking any other medicine containing paracetamol or tramadol, so that you do not exceed the maximum daily doses.

You must not take ZALDIAR together with monoamine oxidase inhibitors ("MAOIs") (see section "Do not take ZALDIAR").

ZALDIAR is not recommended to be taken with the following:

- carbamazepine (a medicine commonly used to treat epilepsy or some types of pain such as severe pain attacks in the face called trigeminal neuralgia).
- buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers). The pain-relieving effect may be reduced.

The risk of side effects increases, if you also take

- triptans (for migraine) or selective serotonin re-uptake inhibitors, "SSRIs" (for depression). If you experience confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles or diarrhoea you should call your doctor.
- tranquillizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), baclofen (a muscle relaxant), medicines used to lower blood pressure, antidepressants or medicines to treat allergies. You may feel drowsy or feel faint. If this happens, tell your doctor.
- antidepressants, anaesthetics, neuroleptics (medicines that affect the state of mind) or bupropion (to help stop smoking). The risk having a fit may increase. Your doctor will tell you whether ZALDIAR is suitable for you.
- warfarin or phenprocoumon (for blood thinning). The effectiveness of such medicines may be altered and bleeding may occur. Any prolonged or unexpected bleeding should be reported to your doctor immediately.

The effectiveness of ZALDIAR may be altered if you also take

- metoclopramide, domperidone or ondansetron (medicines for treatment of nausea and vomiting),
- cholestyramine (medicine to reduce cholesterol in the blood),

- ketoconazole or erythromycin (medicines against infections).

Your doctor will tell you which medicines are safe to take with ZALDIAR.

Taking ZALDIAR with food and drink

ZALDIAR may make you feel drowsy. Alcohol may make you feel more drowsy, so it is best not to drink alcohol while you are taking ZALDIAR.

Pregnancy and breast-feeding

As ZALDIAR contains tramadol, you should not take this medicine during pregnancy. If you become pregnant during treatment with ZALDIAR, please consult your doctor before taking any further tablets. Small amounts of tramadol may pass into the breast-milk. Therefore you should not take this medicine during breast-feeding.

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

Driving and using machines

ZALDIAR may make you feel drowsy and this may affect your ability to drive, or use tools and machines, safely.

Important information about some of the ingredients of Zaldiar

Lactose is an ingredient in these tablets. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to use this product.

Always take ZALDIAR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You should take ZALDIAR for as short a time as possible.

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.

The use in children below the age of 12 years is not recommended.

Unless otherwise prescribed by your doctor, the usual starting dose for adults and adolescents over 12 years is 2 tablets.

If required, further doses may be taken, as recommended by your doctor. The shortest time between doses must be at least 6 hours.

Do not take more than 8 ZALDIAR film-coated tablets per day.

Do not take ZALDIAR more often than your doctor has told you.

Your doctor may increase the time between doses

- if you are older than 75 years,
- if you have kidney problems or
- if you have liver problems.

Method of administration:

The tablets are for oral use.

Swallow the tablets whole with sufficient liquid. They should not be broken or chewed.

If you think that the effect of ZALDIAR is too strong (i.e. you feel very drowsy or have difficulty breathing) or too weak (i.e. you have inadequate pain relief), contact your doctor.

If you take more ZALDIAR than you should:

In such cases please contact your doctor or pharmacist immediately even if you feel well. There is a risk of liver damage which may only show later.

If you forget to take ZALDIAR:

If you forget to take the tablets, pain is likely to return. Do not take a double dose to make up for forgotten individual doses, simply continue taking the tablets as before.

If you stop taking ZALDIAR:

Generally there will be no after-effects when treatment with ZALDIAR is stopped. However, on rare occasions, people who have been taking tramadol for some time may feel unwell if they stop treatment abruptly (see section 4. "Possible Side Effects"). If you have been taking ZALDIAR for some time, you should talk to your doctor if you want to stop because your body may have become used to it.

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).

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

4. Possible side effects

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

Very common: more than 1 out of 10 persons treated;

- nausea,
- dizziness, drowsiness.

Common: less than 1 out of 10, but more than 1 out of 100 persons treated;

- vomiting, digestion problems (constipation, flatulence, diarrhoea), stomach pain, dry mouth,
- itching, sweating,
- headache, shaking,
- confusion, sleep disorders, mood changes (anxiety, nervousness, a feeling of high spirits).

Uncommon: less than 1 out of 100, but more than 1 out of 1,000 persons treated;

- increase in pulse or blood pressure, heart rate or heart rhythm disorders,
- difficulty or pain on passing water,
- skin reactions (for example rashes, hives),
- tingling, numbness or feeling of pins and needles in the limbs, ringing in the ear, involuntary muscle twitching,
- depression, nightmares, hallucinations (hearing, seeing or sensing things that are not really there), memory lapses,
- difficulty swallowing, blood in the stools,
- shivering, hot flushes, pain in the chest,
- difficulty breathing.

Rare: less than 1 out of 1,000, but more than 1 out of 10,000 persons treated;

- fits, difficulties in carrying out coordinated movements,
- addiction,
- blurred vision.

The following are recognised side effects which have been reported by people using medicines that contain only tramadol or only paracetamol. However, if you experience any of these while taking ZALDIAR, you should tell your doctor:

- feeling faint when getting up from a lying or sitting position, slow heart rate, fainting, changes in appetite, muscle weakness, slower or weaker breathing, mood changes, changes in activity, changes in perception, worsening of existing asthma.
- In some rare cases a skin rash, indicating an allergic reaction, may develop with sudden swelling of the face and neck, difficulties breathing or drop of blood pressure and fainting. If this happens to you, stop treatment and see a doctor immediately. You must not take the medicine again.

In rare cases, using a medicine of the type of tramadol may make you become dependent on it, making it hard to stop taking it.

On rare occasions, people who have been taking tramadol for some time may feel unwell if they stop treatment abruptly. They may feel agitated, anxious, nervous or shaky. They may be hyperactive, have difficulty sleeping and have stomach or bowel disorders. Very few people may also get panic attacks,

hallucinations, unusual perceptions such as itching, tingling and numbness, and noise in the ears (tinnitus). If you experience any of these complaints after stopping ZALDIAR, please consult your doctor.

In exceptional cases blood tests may reveal certain abnormalities, for instance, low counts of blood platelets, which may result in nose bleeds or bleeding gums.

Use of ZALDIAR together with medicines used to thin the blood (e.g. phenprocoumon, warfarin) may increase the bleeding risk. Any prolonged or unexpected bleeding should be reported to your doctor immediately.

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.

5. How to store this product

Keep out of the reach and sight of children.

Do not use the ZALDIAR after the expiry date which is printed on the carton and the edge of the blister after [EXP:]. The expiry date refers to the last day of that month.

Do not store above 30°C.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

a. What this product contains

- The active substances are tramadol hydrochloride and paracetamol.

One film-coated tablet contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol.

- The other ingredients are:

Tablet core: powdered cellulose; pregelatinised starch; sodium starch glycolate (type A); maize starch; magnesium stearate.

Film-coating: hypromellose; lactose monohydrate; titanium dioxide (E 171); macrogol 6000; yellow iron oxide (E 172); propylene glycol; talc

b. What this product looks like and contents of the pack

ZALDIAR film-coated tablets are pale yellow film-coated tablets, marked with the logo on one side, marked "T5" on the other side. ZALDIAR film-coated tablets are packed in blister strips. ZALDIAR comes in cartons of 10 and 20 tablets.

c. Marketing Authorization Holder and Manufacturer

Marketing Authorisation holder and responsible for batch release:

STADA Arzneimittel AG

Stadastrasse 2-18

61118 Bad Vilbel

Germany

Bulk Manufacturer:

Farmaceutici Formenti S.p.A.

Via di Vittorio 2

21040 Origgio (VA)

Italy

d. This leaflet was last revised in {MM/YYYY}

April 2014.

THIS IS A MEDICAMENT

- Medicament is a product, which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach of children.

Council of Arab Health Ministers,

Union of Arab Pharmacists