

ZALDIAR film coated tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using ZALDIAR?

ZALDIAR contains the active ingredients tramadol hydrochloride and paracetamol. It is used as a short-term treatment for severe pain, in which other treatments have not worked or can't be given.

For more information, see Section [1. Why am I using ZALDIAR?](#) in the full CMI.

2. What should I know before I use ZALDIAR?

Do not use if you have ever had an allergic reaction to tramadol hydrochloride, paracetamol, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ZALDIAR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZALDIAR and affect how it works.

A list of some of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ZALDIAR?

- The usual starting dose for adults and adolescents over 12 years of age is two tablets. Your doctor should adjust the dose depending on your response. The maximum dose is 8 tablets per day (or 6 tablets if you weigh between 37.5-50 kg).
- Swallow ZALDIAR tablets whole with a glass of water. Do not crush or chew.
- ZALDIAR can be taken with or without meals.

More instructions can be found in Section [4. How do I use ZALDIAR?](#) in the full CMI.

5. What should I know while using ZALDIAR?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ZALDIAR.• Tell your doctor if you feel the dose you are taking is too strong or too weak.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking ZALDIAR, or change the dose, without checking with your doctor.• Do not take ZALDIAR to treat any other conditions unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how ZALDIAR affects you.
Drinking alcohol	<ul style="list-style-type: none">• You must not drink alcohol while using ZALDIAR tablets.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the packaging until it is time to take them.• Keep it in a cool dry place, away from moisture, or heat where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using ZALDIAR?](#) in the full CMI.

6. Are there any side effects?

The most common side effects of ZALDIAR include nausea, dizziness, drowsiness, vomiting, digestion problems (constipation, wind, diarrhoea), stomach pain, dry mouth, itching, sweating, headache, shaking, confusional state, sleep disturbances, and mood changes. Serious side effects or signs of which, include: 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, skin rash, sudden swelling of the face and neck, difficulties breathing, a drop of blood pressure and fainting, and yellowing of the skin and/or eyes (jaundice). On rare occasions, people may experience withdrawal symptoms if they stop taking ZALDIAR abruptly.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING:**Limitations of use**

ZALDIAR should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

ZALDIAR poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

ZALDIAR can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting ZALDIAR and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines & alcohol while using ZALDIAR

Using ZALDIAR with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using ZALDIAR.

ZALDIAR film coated tablets

Active ingredients: *tramadol hydrochloride and paracetamol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZALDIAR.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZALDIAR.

Where to find information in this leaflet:

- [1. Why am I using ZALDIAR?](#)
- [2. What should I know before I use ZALDIAR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ZALDIAR?](#)
- [5. What should I know while using ZALDIAR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ZALDIAR?

ZALDIAR contains a combination of two active ingredients, tramadol hydrochloride and paracetamol.

ZALDIAR is used for the short-term management of severe pain in which other treatments have not worked or can't be given.

Ask your doctor if you have any questions about why ZALDIAR has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use ZALDIAR?

Warnings**Do not use ZALDIAR if:**

- you are allergic to tramadol hydrochloride, paracetamol or any of the ingredients listed at the end of this leaflet.**
 - symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue, or any other parts of the body; rash, itching or hives on the skin.
- you have any of the following health conditions:**
 - severe liver disorder
 - uncontrolled epilepsy
 - a weight less than 37.5 kg.
- you have consumed a lot of alcohol**
- you have taken more than the recommended amount of:**
 - sleeping tablets
 - other medication to relieve pain that your doctor has prescribed or that you have bought from a pharmacy, supermarket or health food shop.
 - psychotropic medications (medicines that affect mood and emotions).
- you are also taking or have taken MAOIs (a type of antidepressant medicine) within the last 14 days.**
- the expiry date on the pack has passed**
- the package shows signs of tampering.**

Check with your doctor if you:

- **have or have had any other medical conditions, especially the following:**
 - 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.
 - kidney problems
 - severe breathing difficulties, such as asthma or have severe lung problems
 - epilepsy or have already experienced fits or seizures
 - recent head injury, shock or severe headaches associated with vomiting
 - any drug dependence
 - taking other medicines to treat pain that contain buprenorphine or pentazocine
 - dehydration
 - eating disorders (anorexia, bulimia)
 - a wasting syndrome including unexplained weight loss, fatigue, weakness and loss of appetite
 - malnutrition (low reserves of glutathione)
 - hypovolaemia (decreased blood volume)
 - metabolic acidosis, a condition that makes blood more acidic.
- **take any medicines for any other condition**
- **have had any allergy to any other medicines, or any other substances, such as foods, preservatives, or dyes.**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

This medicine contains tramadol hydrochloride which should not be taken during pregnancy and breast feeding.

If you become pregnant during treatment, consult your doctor before taking any further tablets.

Use in children

Safety and effectiveness in children younger than 12 years has not been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are taking any other medicines which contain tramadol hydrochloride or paracetamol.

This will ensure you do not exceed the maximum daily doses allowed for tramadol hydrochloride and/or paracetamol.

Some medicines may interfere with ZALDIAR and affect how it works, or vice versa.

Therefore, ZALDIAR is not recommended to be taken with the following:

- carbamazepine, a drug used to treat epilepsy or some types of pain.
- buprenorphine or pentazocine which are also used to treat pain.
- gabapentin or pregabalin which are used to treat epilepsy or pain due to nerve problems (neuropathic pain)
- flucloxacillin, an antibiotic.

The risk of side effects increases if you are taking:

- triptans (for migraine) or selective serotonin reuptake 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.
- certain antidepressants. ZALDIAR 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.
- tranquilizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), baclofen (a muscle relaxant) medicines used to lower blood pressure, medicines to treat allergies. You may feel drowsy or feel faint. If this happens, tell your doctor.
- medicines which may cause convulsions (fits), such as certain antidepressants, antipsychotics, bupropion (used to stop smoking). The risk of having a fit may increase if you take ZALDIAR at the same time.
- Blood thinners such as warfarin. 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 effect of ZALDIAR may be altered if you also take:

- metoclopramide, domperidone or ondansetron, used to treat nausea and vomiting.
- cholestyramine, used to reduce cholesterol in the blood.
- ketoconazole or erythromycin, used to treat infections.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZALDIAR.

This list is not exhaustive.

4. How do I use ZALDIAR?

How much to take

The dosage of ZALDIAR varies with each patient and depends on the intensity of the pain and individual pain sensitivity. In general the *lowest* pain-relieving dose should be taken.

Your doctor will check how well ZALDIAR is working at regular intervals.

The usual starting dose for adults and adolescents over 12 years is two tablets. The shortest time between doses must be at least 6 hours. Additional tablets can be taken as recommended by your doctor.

Do not take more than eight tablets per day.

Patients weighing between 37.5 kg and 50 kg must not take more than six ZALDIAR tablets daily.

Your doctor may reduce the maximum number of tablets you can take each day if you:

- are over 75 years of age
- have mild to moderate liver problems
- have kidney problems.

When to take it

ZALDIAR can be taken with or without meals.

How to take it

Swallow the tablets whole with a full glass of water.

Do not break or chew the tablet.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Do not stop this medicine suddenly.

Your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

ZALDIAR given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

If you forget to take it

The pain is likely to return.

Take it as soon as you remember, and then go back to taking it as before.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much

If you think that you or someone other than you have taken too many ZALDIAR tablets, urgent medical attention is needed.

Keep the person awake by talking to them or gently shaking them every now and then.

Symptoms of overdose include:

- slow, unusual or difficult breathing
- drowsiness, dizziness or unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits
- confusion, memory loss
- difficulty walking
- changes in behaviour or personality.

You should immediately:

- phone triple zero (000) for an ambulance, or
- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Report any other medicine or alcohol which has been taken.

5. What should I know while using ZALDIAR?

Things you should do

- **Remind any doctor, dentist or pharmacist you visit that you are using ZALDIAR.**
- **If you plan to have any surgery or procedure that requires an anaesthetic tell your doctor or dentist that you are taking ZALDIAR.**
- **Before starting any new medicine, tell your doctor or pharmacist that you are taking ZALDIAR.**
- **If you become pregnant while taking ZALDIAR tell your doctor.**
- **Keep all your doctor's appointments so that your progress can be checked.**
- **Tell your doctor if you feel the dose you are taking is too strong or too weak.**

If the dose is too strong you may feel very drowsy or have difficulty breathing. If the dose is too weak you may continue to feel some pain between doses.

Things you should not do

- **Do not stop taking ZALDIAR, or change the dose, without checking with your doctor.**

On rare occasions, especially if you have been taking ZALDIAR for a while stopping treatment abruptly can make you feel unwell.

- **Do not take ZALDIAR to treat any other conditions unless your doctor tells you to.**
- **Do not give your medicine to anyone else, even if they have the same condition as you.**

Driving or using machines

Be careful before you drive, use any machines or tools until you know how ZALDIAR affects you.

It may cause dizziness and drowsiness in some people. Make sure you know how you react to ZALDIAR before you drive a car or do anything else that could be dangerous if you are dizzy. This effect may be made worse by drinking alcohol or some other medicines that act on the central nervous system.

Drinking alcohol

You must not drink alcohol while using ZALDIAR tablets.

Drinking alcohol while taking ZALDIAR may result in severe drowsiness, decreased awareness, breathing problems, coma, and death.

Things to be careful of

Addiction

You can become addicted to ZALDIAR even if you take it exactly as prescribed. ZALDIAR may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking ZALDIAR. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking ZALDIAR suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to ZALDIAR may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Looking after your medicine

Keep your tablets in the packaging until it is time to take them where the temperature stays below 25°C.

Store it in a cool dry place away from moisture, heat or sunlight. For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ZALDIAR.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • nausea • dizziness • drowsiness • vomiting • digestion problems (constipation, indigestion, wind, diarrhoea) • severe stomach pain that may be felt in the back • dry mouth • itching • sweating • headache • fever and chills • confusional state • sleep disturbances such as a sudden awakening from sleep with shortness of breath • trouble with sleeping (either not enough or too much) • snoring • mood change. 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>
<ul style="list-style-type: none"> • trouble swallowing • chest discomfort such as pressure, heartburn or tightness. 	<p>Speak to your doctor if you have any of these side effects that may be associated with long-term use.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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. 	<p>Tell your doctor immediately if you notice any of these serious side effects.</p>

<p>Signs of withdrawal after stopping ZALDIAR:</p> <ul style="list-style-type: none"> • feeling agitated, anxious, nervous or shaky • panic attacks • hallucinations • unusual perceptions, such as itching, tingling and numbness, noise in the ears (tinnitus). 	
<ul style="list-style-type: none"> • severe skin rash • sudden swelling of the face and neck • difficulties breathing • drop of blood pressure and fainting • yellowing of the skin and /or eyes, also called jaundice. 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ZALDIAR contains

<p>Active ingredients (main ingredients)</p>	<ul style="list-style-type: none"> • tramadol hydrochloride 37.5 mg/tablet • paracetamol 325 mg/tablet
<p>Other ingredients (inactive ingredients)</p>	<p>Tablet core contains:</p> <ul style="list-style-type: none"> • powdered cellulose • pregelatinized maize starch • sodium starch glycollate (type A) • maize starch • magnesium stearate.

	<p>Film-coating light yellow contains:</p> <ul style="list-style-type: none"> • hypromellose • lactose monohydrate • titanium dioxide • macrogol 6000 • iron oxide yellow • propylene glycol • purified talc.
<p>Potential allergens</p>	<ul style="list-style-type: none"> • lactose monohydrate.

Do not take this medicine if you are allergic to any of these ingredients.

What ZALDIAR looks like

ZALDIAR are pale yellow film-coated tablets, marked with the manufacturer's logo on one side and 'T5' on the other side. Available in blister packs of 20 or 50 tablets.

Australian Registration number: AUST R 179677.

Who distributes ZALDIAR

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos St
St Leonards NSW 2065
Australia

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