

ZOTREN 4 & 8

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.

1. Why am I using ZOTREN?

ZOTREN contains the active ingredient ondansetron (as hydrochloride dihydrate). ZOTREN is used to help stop the nausea (sick feeling) and vomiting which can occur after medical treatments and operations.

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

2. What should I know before I use ZOTREN?

Do not use if you have ever had an allergic reaction to ondansetron 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 ZOTREN?](#) in the full CMI.

3. What if I am taking other medicines?

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

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

4. How do I use ZOTREN?

- Take ZOTREN as directed by your doctor or pharmacist.
- Do NOT take MORE TABLETS than your doctor or pharmacist tells you.

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

5. What should I know while using ZOTREN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ZOTREN.• Tell your doctor if you become pregnant or are trying to become pregnant
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or change the dose without first checking with your doctor.• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.• Do not use ZOTREN to treat any other complaints unless your doctor says to.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving, operating machinery while you are taking ZOTREN until you know how it affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep ZOTREN in a cool, dry place where it stays below 25°C.• Keep ZOTREN in their blister pack until time to take.

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

6. Are there any side effects?

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.

ZOTREN 4 & 8

Active ingredient(s): Ondansetron (as hydrochloride dihydrate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZOTREN. **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 ZOTREN.**

Where to find information in this leaflet:

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

1. Why am I using ZOTREN?

ZOTREN contains the active ingredient ondansetron (as hydrochloride dihydrate). ZOTREN belongs to a group of medicines called serotonin receptor-3 antagonists. **ZOTREN is used to help stop the nausea (sick feeling) and vomiting which can occur after medical treatments and operations.**

ZOTREN should only be used to treat the nausea and vomiting for which they have been prescribed.

Your doctor may have prescribed ZOTREN for another reason. If you want more information, ask your doctor.

ZOTREN is not addictive.

2. What should I know before I use ZOTREN?

Warnings

Do not use ZOTREN if:

- you are taking apomorphine (used to treat Parkinson's disease);
- you have ever had an allergic reaction to ondansetron or any of the ingredients listed toward the end of this leaflet (see "Ingredients");

Check with your doctor if you:

- you are allergic to foods, dyes, preservatives or any other medicines;
- you have had to stop taking another medicine for your nausea or vomiting;

- you are taking any other medicines, including medicines you buy without a prescription;
- you have or used to have liver problems; or
- you are breastfeeding, pregnant or trying to become pregnant.

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

Do not take ZOTREN if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says it is safe;

Your doctor will discuss the risks and benefits of using ZOTREN if you are pregnant or breastfeeding.

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.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking ZOTREN with other medicines.

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

4. How do I use ZOTREN?

How much to take

- Take ZOTREN as directed by your doctor or pharmacist
- Do NOT take MORE TABLETS than your doctor or pharmacist tells you.
- Do NOT take the tablets MORE OFTEN than your doctor or pharmacist tells you.
- If you vomit within one hour taking your first ZOTREN tablet of each course prescribed to you, you should take the same dose again. If you continue to vomit, tell your doctor.

How to take ZOTREN

Swallow each tablet with a drink of water. Do not crush the tablet. If you have trouble swallowing your tablet, please tell your doctor.

How to long to take ZOTREN for

Do not stop taking ZOTREN, or change dose without first checking with your doctor.

If you forget to use ZOTREN

If you miss your dose and you do not feel sick, take your next dose when you are meant to.

If you miss your dose and you feel sick, take the missed dose as soon as possible, then go back to taking ZOTREN as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

If you use too much ZOTREN

If you think that you have used too much ZOTREN, you may need urgent medical attention.

You should immediately:

- 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.

5. What should I know while using ZOTREN?

Things you should do

Call your doctor straight away if you:

- Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.
- Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use ZOTREN to treat any other complaints unless your doctor says to.

Driving or using machines

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

Looking after your medicine

- Keep ZOTREN in their blister pack until time to take.

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.

When to discard your medicine

If your doctor tells you to stop taking ZOTREN or it is out of date.

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.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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">• Headache;• A sensation of warmth or flushing;• Mild stomach cramps;• Constipation or diarrhoea;• Dry mouth; or• Hiccups.	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• 'Wheezy' symptoms;• Chest pain or tightness of the chest;• Changes in the way your heart beats, e.g. if you notice it beating faster or slower than normal, or if it beats irregularly or if it 'throbs';• Disturbance in heart rhythm (sometimes causing a sudden loss of consciousness);• Patients may experience "serotonin syndrome" (confusion, sweating, unsteadiness, shaking, diarrhoea) when ZOTREN is	<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>

taken in combination with other serotonergic drugs. Serotonergic drugs can include certain types of antidepressants, opioid pain medicines such as tramadol and fentanyl, and lithium. Please note, this is not an exhaustive list. Please discuss with your pharmacist or doctor if you have any concerns;

- Severe skin reaction where the top layer of the skin detaches from the lower layers;
- Low blood pressure;
- Fits or convulsions;
- Swelling of the eyelids, face, lips, mouth or throat which may cause difficulty in swallowing or breathing; or
- Skin rash, skin lumps or hives.

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.

In certain illnesses and treatments where ZOTREN has been used, blood vessel blockage has occurred.

However, it is important to note that blood vessel blockage has also occurred in these illnesses and treatments when ZOTREN has NOT been used. Discuss this with your doctor if you have any concerns.

If you feel unwell or have any symptoms that you do not understand, you should tell your doctor immediately.

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 ZOTREN contains

Active ingredient (main ingredient)	Ondansetron hydrochloride dihydrate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Lactose;• Cellulose microcrystalline;• Magnesium stearate;• Starch-pregelatinised maize;• The 4 mg tablet also contains triacetin, titanium dioxide and hypromellose; and• The 8 mg tablet also contains Opadry yellow 03K52033.
Potential allergens	This medicine contains sugars as lactose.

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

What ZOTREN looks like

ZOTREN 4: White to off-white, oval shaped, film-coated tablets debossed with 'E' on one side and '01' on the other side (Aust R 287601).

ZOTREN 8: Yellow coloured, oval shaped, film-coated tablets debossed with 'E' on one side and '02' on the other side. (AUST R 287602)

Do NOT use your tablets if they have changed colour.

Who distributes ZOTREN

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
Cremorne, VIC 3121
Australia

This leaflet was prepared in September 2023.