

ZOTREN ODT 4 & 8

Ondansetron 4 mg and 8 mg orally disintegrating tablets

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking ZOTREN ODT.

This leaflet answers some common questions about ZOTREN ODT. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ZOTREN ODT against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ZOTREN ODT is used for

ZOTREN ODT belongs to a group of medicines called antiemetics.

ZOTREN ODT works by helping to stop the nausea (sick feeling) and vomiting which can occur after certain treatments.

ZOTREN ODT should only be used to treat the nausea and vomiting for which it has been prescribed.

Your doctor may have prescribed ZOTREN ODT for another reason.

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

ZOTREN ODT is not addictive.

Before you take ZOTREN ODT

When you must not take them

- **Do not take ZOTREN ODT if you are taking apomorphine (used to treat Parkinson's disease)**
- **Do not take ZOTREN ODT if you have ever had an allergic reaction to ondansetron or any of the ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash ("hives") or fainting.
- **Do not take ZOTREN ODT if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.**
Your doctor will discuss the risks and benefits of using ZOTREN ODT if you are pregnant or breastfeeding.
- **Do not take ZOTREN ODT after the expiry date (EXP) printed on the pack.**
If you take it after the expiry date has passed, it may not work as well.
- **Do not take ZOTREN ODT if the packaging is torn or shows signs of tampering.**

If you're not sure whether you should be taking ZOTREN ODT, talk to your doctor.

Before you start to take them

You must tell your doctor if:

- you are allergic to foods, dyes, preservatives or any other medicines;
- you have, or used to have, liver problems;
- you suffer from severe constipation or have a blockage in your gut; or
- you have phenylketonuria, as ZOTREN ODT contains aspartame.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a 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 ODT with other medicines.

Use in children

There is limited experience in children. ZOTREN ODT can be taken by children over 4 years of age.

How to take it

The Pharmacist's label on the pack will tell you how to take ZOTREN ODT. If there is something you do not understand, ask your doctor or pharmacist.

How much to take

DO NOT take more ZOTREN ODT than your doctor or pharmacist tells you.

DO NOT take ZOTREN ODT more often than your doctor or pharmacist tells you.

If you vomit within one hour of taking your first ZOTREN ODT of each course prescribed for you, you should take the same dose again. If you continue to vomit, tell your doctor.

How to take them

PEEL BACK the foil top of the blister strip and GENTLY remove the ZOTREN ODT. (DO NOT try to push it through the foil top as the tablet is fragile and will break up inside the foil). Place the ZOTREN ODT on top of your tongue. It will disappear very quickly, then swallow as normal.

When to take them

Your doctor or pharmacist will be able to tell you when you should take your ZOTREN ODT.

How long to take them

Your doctor or pharmacist will be able to tell you how long you should take your ZOTREN ODT.

If you forget to take them

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 your ZOTREN ODT 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 take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, if you think you or

anyone else may have taken too much ZOTREN ODT, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

While you are taking it

Things you must do

Tell your doctor or pharmacist that you are taking ZOTREN ODT if you are about to be started on any new medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not stop taking ZOTREN ODT, 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 ODT to treat any other complaints unless your doctor says to.

Side effects

Check with your doctor as soon as possible if you have any problems while taking ZOTREN ODT, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, ZOTREN ODT can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side effects are:

- headache;
- a sensation of warmth or flushing;
- mild stomach cramps;
- constipation or diarrhoea;
- dry mouth;
- hiccups; or
- dizziness or light-headed feeling.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist immediately if you notice any of the following:

- chest pain or tightness of 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);
- low blood pressure;
- abnormal muscular body movements or shaking;

- involuntary upward movement of the eyes;
- unusual muscle tone causing distortion of the body;
- fits or convulsions;
- patients may experience "serotonin syndrome" (confusion, sweating, unsteadiness, shaking, diarrhoea) when ZOTREN ODT is taken in combination with other serotonergic drugs. Serotonergic drugs can include certain types of antidepressants and 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.

If you think you are having an allergic reaction to ZOTREN ODT, TELL YOUR DOCTOR IMMEDIATELY or go to the casualty department at your nearest hospital. Symptoms usually include some or all of the following:

- wheezing;
- swelling of the lips/mouth;
- difficulty in breathing;
- hay fever;
- lumpy rash ("hives"); or
- fainting.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

If your nausea (feeling of sickness) or vomiting does not go away, ask your doctor what to do.

In certain illnesses and treatments where ZOTREN ODT 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 ODT has NOT been used. Discuss this with your doctor if you have any concerns.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

After taking it

Storage

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep ZOTREN ODT in a cool, dry & dark place where it stays below 25°C.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your ZOTREN ODT in their pack until it is time to take them.

If taken out of their pack, they may not keep well.

Disposal

If your doctor tells you to stop taking ZOTREN ODT, or they have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What it looks like

ZOTREN ODT 4 & 8 (4 & 8 mg ondansetron) are presented in pack sizes* of 4, 10 & 20 tablets in blister.

ZOTREN ODT 4 (AUST R 287603)

White to off-white, round tablets debossed with '5' on one side and 'E' on the other side with an embossed circular edge.

ZOTREN ODT 8 (AUST R 287604)

White to off-white, round tablets debossed with '7' on one side and 'E' on the other side with an embossed circular edge.

Ingredients

Active ingredient

Ondansetron

Inactive ingredients

- mannitol;
- crospovidone;
- lactose monohydrate;
- microcrystalline cellulose;
- aspartame;
- colloidal anhydrous silica;
- magnesium stearate; and
- strawberry guarana 586997 AP0551.

This medicine contains lactose and aspartame.

*Some of these pack sizes are not marketed.

Sponsor/Marketing Authorisation Holder

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne
Victoria 3121
Australia

This leaflet was prepared in November 2021.