

## Zofran® Syrup

Ondansetron hydrochloride dihydrate

### Consumer Medicine Information

#### What is in this leaflet

Please read this leaflet carefully before you start taking Zofran Syrup.

This leaflet answers some common questions about Zofran Syrup. 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 Zofran Syrup 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 Zofran Syrup is used for

Zofran syrup contains ondansetron which is used to help stop the nausea (sick feeling) and vomiting which can occur after certain treatments. Zofran syrup should only be used to treat the nausea and vomiting for which it has been prescribed.

Your doctor may have prescribed Zofran syrup for another reason.

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

Zofran syrup is not addictive.

#### Before you take Zofran Syrup

##### When you must not take it

- **Do not take Zofran syrup if you are taking apomorphine (used to treat Parkinson's disease).**
- **Do not take Zofran syrup if you have ever had an allergic reaction to ondansetron hydrochloride dihydrate 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, hayfever, lumpy rash ("hives") or fainting.
- **Do not take Zofran syrup 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 Zofran Syrup if you are pregnant or breastfeeding.
- **Do not take Zofran Syrup 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 Zofran syrup if the packaging is torn or shows signs of tampering.**

**If you're not sure whether you should be taking Zofran syrup, talk to your doctor.**

##### Before you start to take it

You must tell your doctor if:

- 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 have or used to have liver problems.

#### 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 Zofran syrup with other medicines.

#### How to take Zofran Syrup

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

##### How much to take

The usual dosage for adults is 8 mg (10 mL) twice daily for up to 5 days.

The usual dosage for children is 4 mg (5 mL) twice daily for up to 5 days.

##### How to take it

Your Zofran syrup should be swallowed.

##### When to take it

Your doctor or pharmacist will be able to tell you when you should take your Zofran syrup.

If you vomit within one hour of taking your dose of Zofran syrup, you should take the same dose again. If you continue to vomit, tell your doctor.

##### How long to take it

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

##### If you forget to take it

**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 Zofran syrup 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 Zofran syrup, 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 Zofran Syrup

##### Things you must do

**Tell your doctor or pharmacist that you are taking Zofran syrup 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 Zofran syrup, 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 Zofran syrup 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 Zofran syrup, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.**

Like other medicines, Zofran Syrup 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.

**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:**

- fits or convulsions
- low blood pressure
- changes in the way your heart beats eg. 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 Zofran is 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.

**If you think you are having an allergic reaction to Zofran syrup, 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")
- fainting.

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

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

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.

**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.**

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## After taking Zofran Syrup

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### *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 Zofran syrup in a cool, dry place where it stays below 30°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 medicine in its pack until it is time to take it.**

If you take the medicine out of its pack it may not keep well.

### *Disposal*

**If your doctor tells you to stop taking Zofran syrup, or the medicine has passed its expiry date, ask your pharmacist what to do with any medicine left over.**

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## Product description

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### *What Zofran syrup looks like*

Your Zofran syrup is a clear, colourless to light yellow liquid, with a strawberry flavour. Each bottle contains 50 mL syrup.

DO NOT use your syrup if it has changed colour.

### *Ingredients*

Each 5 mL contains 4 milligrams of ondansetron (as hydrochloride).

Your syrup also contains the following inactive ingredients: citric acid (330), sodium citrate dihydrate, sodium benzoate (211), sorbitol solution (420), strawberry flavour (contains ethanol) and purified water.

### *Manufacturer*

Your Zofran syrup is supplied by:  
**Aspen Pharmacare Australia Pty Ltd**  
34-36 Chandos Street  
St Leonards NSW 2065  
Australia

### *Further Information*

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

**Do not throw this leaflet away.**

You may need to read it again.

This leaflet was updated in October 2014.

The information provided applies only to:  
Zofran® Syrup.

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