

ZOFRAN® Injection

Ondansetron hydrochloride dihydrate

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you use Zofran Injection.

This leaflet answers some common questions about Zofran Injection. 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 expected benefits of you taking Zofran Injection against the risks this medicine could 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 is Zofran Injection used for?

Zofran Injection contains a medicine called ondansetron. This belongs to a group of medicines called serotonin receptor-3 antagonists.

Zofran Injection is used to help stop the nausea (sick feeling) and vomiting which can occur after medical treatments and operations.

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

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

Zofran Injection is not addictive.

Before you take Zofran Injection

Do not take if:

You must not take Zofran Injection 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")
- you are pregnant, trying to become pregnant or breast feeding, unless your doctor says it is safe.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.
- the injection solution is coloured, cloudy or lumpy.

Tell your doctor if:

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

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

How do I take Zofran Injection?

Your Zofran Injection must only be given by a doctor or nurse.

Sometimes other medicines are given at the same time.

Do NOT use the Injection on your own.

The clinical safety of Zofran in children under 2 years has not been studied.

While you are taking Zofran Injection

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Zofran Injection to treat any other complaints unless your doctor says to.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Zofran Injection, even if the problem is not listed below.

Like other medicines, Zofran Injection 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
- burning sensation at the site of injection.

These are all mild side effects. There is no immediate reason to stop taking your Injection unless you are concerned.

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

- '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 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
- low blood pressure

- fits or convulsions
- swelling of the eyelids, face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- skin rash, skin lumps or hives
- blurred vision
- dizziness.

These are all serious side effects. You may need urgent medical attention. Serious side effects are rare.

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.

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

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 Injection 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.

How do I store Zofran Injection?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Keep Zofran Injection in a cool, dry place where it stays below 30°C, and away from bright sunlight.

Do not leave in a car, on window sill or in bathroom.

Keep Zofran Injection ampoules in their blister pack until time to take.

Return any unused or expired medicine to your pharmacist.

Product description

What Zofran Injection looks like

Each ampoule contains ondansetron in 2 mL or 4 mL clear aqueous solution.

Each pack will contain one, five or ten ampoules.

Ingredients

Each injection contains either 4 or 8 milligrams of the active ingredient ondansetron. Your doctor will decide which strength you need.

Zofran Injection also contain small amounts of citric acid, sodium citrate and sodium chloride.

Manufacturer

Your Zofran Injection is made by:
Aspen Pharmacare Australia Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

Where to go for 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.

This leaflet was updated in October 2014.

The information provided applies only to: Zofran Injection.

Zofran® is a registered trademark of Aspen Global Incorporated.

Zofran Injection 4 mg/2 mL: AUST R 9978

Zofran Injection 8 mg/4 mL: AUST R 47264

This leaflet is subject to copyright.