

ZOFRAN[®] TABLET

Ondansetron hydrochloride dihydrate (4mg, 8mg)

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What ZOFRAN is used for

It is used to prevent and manage nausea (feeling sick) and vomiting (being sick), which can occur:

- during treatment for cancer (chemotherapy or radiotherapy)
- after an operation

How ZOFRAN works

Zofran belongs to a group of medicines called anti-emetics.

Before you use ZOFRAN

- When you must not use it

Do not take Zofran

- if you are taking apomorphine (used to treat Parkinson's disease, a movement disorder)
- if you are allergic (hypersensitive) to ondansetron or any other ingredients of Zofran

If you think this applies to you, do not use Zofran until you have checked with your doctor.

- Before you start to use it

Before you use Zofran your doctor needs to know:

- if you are allergic to medicines similar to Zofran, such as medicines containing granisetron or palonosetron

- if you have ever had heart problems, such as an irregular heartbeat (arrhythmia)
- if you have bowel problems
- if you have electrolyte abnormalities
- if you have liver disease, your doctor may lower your dose of Zofran

Check with your doctor if you think any of these may apply to you.

Zofran is not recommended for use during pregnancy.

- Tell your doctor if you are pregnant or planning to become pregnant.
- If you do become pregnant during treatment with Zofran, tell your doctor.

Breast-feeding is not recommended during treatment with Zofran. The ingredients can pass into your breast milk, and may affect your baby. Talk to your doctor about this.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, if you have taken any recently, or if you start taking new ones. This includes medicines bought without a prescription.

- carbamazepine or phenytoin (used to treat epilepsy)
- rifampicin (used to treat bacterial infections such as tuberculosis (TB))
- tramadol (a pain killer)

How to use ZOFRAN

- How much to use

Always take Zofran exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

To prevent you from feeling sick and vomiting after cancer treatment.

On the day of treatment:

- The usual dose of Zofran is 8 mg to be taken one to two hours before treatment, followed by 8 mg every 12 hours.

On the following days:

Adults

- The usual dose is 8 mg twice a day, for up to 5 days
- Children and Adolescents (aged 3 years to 17 years)
- Your doctor will decide on the correct dose of Zofran for your child. The usual dose is up to 8 mg a day, for up to 5 days.

To prevent you from feeling sick and vomiting after an operation

Adults

- The usual adult dose is 16 mg one hour before your operation.
- Children and Adolescents (aged 3 years to 17 years)
- Zofran tablets are not recommended for use in children after an operation

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Take Zofran for as long as your doctor recommends. Do not stop unless your doctor advises you to.

- If you forget to use it

Take your dose as soon as possible then take your next dose at the usual time. Do not

take a double dose to make up for a missed dose.

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

- *If you use too much (overdose)*

If you accidentally use too much Zofran, it is unlikely to cause you any problems. But if you are worried, or you feel unwell, ask your doctor or pharmacist for advice.

While you are using it

- *Things you must do*

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

Swallow the tablets whole with a glass of water.

Tell your doctor or nurse if you continue to feel sick.

- *Things you must not do*

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- *Things to be careful of*

Zofran tablets are not recommended for use in children and Adolescents (aged 3 years to 17 years) after an operation.

Side Effects

Like all medicines, Zofran can cause side effects, but not everybody gets them.

Severe allergic reactions

These are rare severe allergic reactions in people taking Zofran. Signs include:

- raised and itchy rash (hives)
- swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing
- collapse

Contact a doctor immediately if you get these symptoms. Stop taking Zofran.

Very common side effects

These may affect more than 1 in 10 people:

- headache

Common side effects

These may affect up to 1 in 10 people:

- feeling of warmth or flushing
- constipation

Uncommon side effects

These may affect up to 1 in 100 people:

- fits (*seizures*)
- involuntary muscle movements or spasms
- irregular or slow heartbeat
- chest pain
- low blood pressure
- hiccups

Uncommon side effects which may show up in blood tests:

- increases in substances (*enzymes*) produced by the liver.

Rare side effects

These may affect up to 1 in 1,000 people:

- severe allergic reactions
- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)
- dizziness
- temporary blurred or altered vision

Very rare side effects

These may affect up to 1 in 10,000 people:

- temporary blindness
- toxic skin eruption

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of ZOFRAN

- *Storage*

Keep out of the reach and sight of children.

Do not use Zofran after the expiry date shown on the pack. Store Zofran below 30°C (86°F).

- *Disposal*

Do not dispose of medicines in your wastewater or household rubbish. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

Product Description

- *What it looks like*

Zofran Tablets 4 mg:

Yellow, oval, biconvex tablet engraved 'GX ET3' on one face and plain on the other face

Zofran Tablets 8 mg:

Yellow, oval, biconvex tablet engraved 'GX ET5' on one face and plain on the other face

ZOFRAN tablets are available in blister packs of 30's.

- *Ingredients*

- Active ingredient(s)

Each tablet contains either 4 mg or 8 mg ondansetron.

- Inactive ingredient(s)

Lactose, Microcrystalline cellulose, Pregelatinised maize starch, Magnesium stearate, Methylhydroxypropylcellulose,

Titanium dioxide (E171) , Iron oxide (E172), Opadry yellow, industrial methylated spirit.

- *MAL number*

Zofran Tablet 4 mg:

- MAL19950007ACR

Zofran Tablet 8 mg:

- MAL19950013ACR

Manufacturer

Aspen Bad Oldesloe GMBH
Industriestrasse 32 – 26, 23843,
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Product Registration Holder

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