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. Ondansetron is a $5HT_3$ receptor antagonist. It works by inhibiting the $5HT_3$ receptors on neurons located in peripheral and central nervous system of the body.

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 liver disease, your doctor may lower your dose of Zofran
- if you are taking other medicines (interactions with other medicinal products including vaccines or biologics)

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

Pregnancy and breast-feeding

Zofran is not recommended for use during pregnancy.

- Tell your doctor if you are pregnant or planning to become pregnant. Zofran may harm your unborn baby.
- 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.

Females of child-bearing potential and male patients

If you are a woman of childbearing age, your doctor will check if you are pregnant and perform a pregnancy test if necessary before starting treatment with Zofran. If you may become pregnant, you should use effective birth control during treatment and for at least 2 days after stopping Zofran.

Ask your doctor about options of effective birth control.

- *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 infections such as tuberculosis (TB), type of bacterial infection)
- fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram (SSRIs [selective serotonin reuptake inhibitors]) (used to treat depression and/or anxiety)
- venlafaxine, duloxetine (SNRIs [serotonin noradrenaline reuptake inhibitors]) (used to treat depression and/or anxiety)
- 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 (ages 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 (ages 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*

Tell your doctor or pharmacist immediately if you get any of these symptoms during and after the treatment with Zofran.
- if you experience sudden chest pain or chest tightness (myocardial ischemia).

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.

Some side effects could be serious
STOP taking or receiving Zofran and seek medical help immediately if you experience any of the following:

Severe allergic reactions
These are rare in people taking Zofran. Signs include:
- raised and itchy rash (hives)
- swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing
- collapse

Myocardial ischemia: Signs include:
- sudden chest pain or
- chest tightness

Other possible side effects
Other side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.

Very common: may affect more than 1 in 10 people
- headache

Common: may affect up to 1 in 10 people
- feeling of warmth or flushing
- constipation

Uncommon: 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
- increases in substances (*enzymes*) produced by the liver (may show up in blood test).

Rare: 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: may affect up to 1 in 10,000 people:
- a widespread rash with blisters and skin peeling on much of the body surface (*toxic epidermal necrolysis*)
- temporary blindness

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

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).

- *MAL number*

Zofran Tablet 4 mg:
- MAL19950007ACRZ

Zofran Tablet 8 mg:
- MAL19950013ACRZ

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Product Registration Holder
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Information issued
10/03/2021

Date of Revision
28/08/2026

Serial Number
NPRA (R1/3) 31012024/027