PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed according to a physician's prescription only

Zofran® Tablets 4 mg

Ondansetron (as hydrochloride dihydrate) 4 mg per tablet.

Zofran® Tablets 8 mg

Ondansetron (as hydrochloride dihydrate) 8 mg per tablet.

List of the additional ingredients detailed in section 6.
See also "Important information about some ingredients of the medicine" in section 2.

Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Zofran tablets are used for:
- treating nausea and vomiting caused by chemotherapy (in adults and children) or radiotherapy (adults only).
- preventing and treating nausea and vomiting after surgery (adults only).

Therapeutic group
Serotonin receptor antagonist ($5HT_3$).

Zofran tablets contain an active ingredient called ondansetron. Zofran belongs to a group of medicines called anti-emetics.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- you are taking apomorphine (used to treat Parkinson's disease).
- you are sensitive (allergic) to ondansetron or to any of the other ingredients contained in the medicine (listed in Section 6).

If you are not sure, talk to your physician or pharmacist before taking Zofran tablets.

Special warnings regarding the use of the medicine
Before the treatment with Zofran, tell the physician if:
- you have ever had heart problems (e.g., congestive heart failure which causes shortness of breath and swollen ankles)
- you have irregular heartbeat (arrhythmias)
- you have congenital long QT syndrome in ECG. The medicine should be administered with caution to patients who may develop prolongation of QT, in particular patients with electrolyte abnormalities, heart failure, bradyarrhythmias or patients taking other medical supplements that may lead to QT prolongation or electrolyte abnormalities
- you are allergic to medicines similar to ondansetron, such as granisetron or palonosetron
- you have liver problems
- you have a blockage in your gut
- you are going to undergo adenotonsillar surgery, as the medicine may mask occult bleeding
- you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium

If you are not sure if any of the above apply to you, talk to your physician or pharmacist before taking Zofran tablets.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines, herbal medicines and food supplements, tell the physician or the pharmacist. This is because Zofran can affect the way some medicines work. Also, some other medicines can affect the way Zofran works. Especially inform the physician or the pharmacist if you are taking:
- carbamazepine or phenytoin used to treat epilepsy
- rifampicin used to treat infections such as tuberculosis (TB)
- antibiotics such as erythromycin
- antifungal medicines such as ketoconazole
- anti-arrhythmic medicines used to treat irregular heartbeat
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or to prevent migraines
- tramadol and fentanyl, painkillers
- medicines that affect the heart (such as haloperidol or methadone)
- cancer medicines (especially anthracyclines and trastuzumab)
- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram. There have been reports about the development of serotonin syndrome following the concomitant use of these drugs with Zofran.
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine, duloxetine. There have been reports about the development of serotonin syndrome following the concomitant use of these drugs with Zofran.
- other medicines that can cause serotonin syndrome such as mirtazapine for the treatment of depression, monoamine oxidase inhibitor drugs for the treatment of Parkinson's, lithium for the treatment of psychiatric disorders or injectable methylene blue.

If you are not sure if any of the above apply to you, talk to your physician or pharmacist before taking Zofran tablets.

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

Pregnancy, breastfeeding and fertility
- If you are pregnant, think you may be pregnant or are planning to be pregnant, consult your physician or pharmacist before taking Zofran, since Zofran may slightly increase the risk that your baby will be born with a cleft palate (partial or complete palate closure defect).
- Do not breastfeed if you are taking Zofran. This is because small amounts pass into the mother's milk. Ask your physician for advice.

Important information about some ingredients of the medicine
This medicine contains lactose:
Each 4 mg Zofran tablet contains 81.875 mg lactose anhydrous
Each 8 mg Zofran tablet contains 163.75 mg lactose anhydrous
If you have been told by your physician that you have an intolerance to some sugars, talk to your physician before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use Zofran according to the physician's instructions.
You should check with the physician or the pharmacist if you are uncertain regarding the dosage and treatment regimen of Zofran.
The dosage and treatment regimen will be determined by the physician only. The dose you have been prescribed depends on the treatment you are receiving.

To treat nausea and vomiting from chemotherapy or radiotherapy (adults only)
On the day of chemotherapy or radiotherapy
- the usual adult dose is 8 mg taken one to two hours before treatment and another 8 mg taken 12 hours after the first dose.

On the following days
- the usual adult dose is 8 mg twice a day
- the treatment may be given for up to 5 days.

Children:
To treat nausea and vomiting from chemotherapy
The physician will decide the dose depending on the child's size (body surface area).

To prevent and treat nausea and vomiting after an operation (adults only)
The usual adult dose is 16 mg before your operation.

Patients with moderate or severe liver problems (adults only)
The total daily dose should not be more than 8 mg.

Zofran tablets will start working within one or two hours of taking a dose.

Do not exceed the recommended dose

If you are sick (vomit) within one hour of taking a dose
- take the same dose again
- otherwise, do not take more Zofran tablets than the physician ordered.

If you continue to feel sick, tell your physician.

The tablets are film-coated and should not be crushed, halved or chewed.

If you accidently have taken a higher dosage
If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine
If you missed a dose **and** feel sick or vomit:
- take Zofran tablets as soon as possible, then
- take your next tablet at the usual time.
- do not take a double dose to make up for a forgotten dose.

If you missed a dose but do not feel sick:
- take the next dose at the usual time.
- do not take a double dose to make up for a forgotten dose.

Persist with the treatment as recommended by the physician.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Zofran may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Some side effects could be serious

Stop taking Zofran and seek medical help immediately if you or your child experience any of the following:

Allergic reactions
- sudden wheezing and chest pain or chest tightness
- swelling of the eyelids, face, lips, mouth or tongue
- skin rash - red spots or lumps under your skin (hives) anywhere on your body
- collapse

Myocardial ischemia
- sudden chest pain or
- chest tightness

Other side effects
Very common (may occur in more than 1 in 10 people)
- headache

Common (may occur in up to 1 in 10 people)
- a feeling of warmth or flushing
- constipation
- changes to liver function test results (if you take Zofran tablets with a medicine called cisplatin, otherwise this side effect is uncommon)

Uncommon (may occur in up to 1 in 100 people)
- hiccups
- low blood pressure, which can make you feel faint or dizzy
- uneven heartbeat
- chest pain
- fits
- unusual body movements or shaking

Rare (may occur in up to 1 in 1,000 people)
- feeling dizzy or lightheaded
- blurred vision
- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)

Very rare (may occur in up to 1 in 10,000 people)
- poor vision or temporary loss of eyesight, which usually comes back within 20 minutes

If you get any side effect, if any of the side effects get worse, or when you suffer from side effect not mentioned in the leaflet, you should consult the physician.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects,
or by entering the link:
https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store below 30°C.
- Do not dispose of medicines in the wastewater or household waste bin. Consult the pharmacist about where to dispose of medicines that are not in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient the medicine also contains
  Lactose (anhydrous), microcrystalline cellulose, pre-gelatinised maize starch, methylhydroxypropylcellulose, magnesium stearate, titanium dioxide (E171) and iron oxide yellow (E172).
- What does the medicine look like and what is the content of the package
  Zofran tablets are yellow, oval, film-coated tablets marketed in two strengths.
  The 4 mg tablets contain 4 mg of the active ingredient ondansetron and are marked with "GXET3" on one face and plain on the other.
  The 8 mg tablets contain 8 mg of the active ingredient ondansetron and are marked with "GXET5" on one face and plain on the other.
- Zofran tablets are marketed in:
  blister packs of 10 tablets.
- Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.
- Revised on March 2022 according to MOH guidlines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
  Zofran Tablets 4 mg 049 96 26549
  Zofran Tablets 8 mg 049 95 26560