

Zofran® 4 mg Tablets

Zofran® 8 mg Tablets

(ondansetron hydrochloride dihydrate)

1937/1938
15.06.20[14]

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions about your illness or your medicine, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Zofran 4mg Tablets or Zofran 8mg Tablets but will be referred to as Zofran tablets throughout this leaflet.

What is in this leaflet:

1. What Zofran tablets are and what they are used for
2. What you need to know before you take Zofran tablets
3. How to take Zofran tablets
4. Possible side effects
5. How to store Zofran tablets
6. Contents of the pack and other information

1. WHAT ZOFRAN TABLETS ARE AND WHAT THEY ARE USED FOR
Zofran tablets contain a medicine called ondansetron. This belongs to a group of medicines called anti-emetics.

Zofran tablets are used for:

- preventing nausea and vomiting caused by chemotherapy (in adults and children) or radiotherapy for cancer (adults only)
- preventing nausea and vomiting after surgery (adults only).

Ask your doctor, nurse or pharmacist if you would like any further explanation about these uses.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZOFRAN TABLETS

Do not take Zofran tablets if:

- you are taking apomorphine (used to treat Parkinson's disease)
- you are allergic (hypersensitive) to ondansetron or any of the other ingredients in Zofran tablets (listed in Section 6).

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

Warnings and precautions

Check with your doctor, nurse or pharmacist before taking Zofran tablets if:

- you have ever had heart problems (e.g. congestive heart failure which causes shortness of breath and swollen ankles)
- you have an uneven heart beat (arrhythmias)
- 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 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 doctor, nurse or pharmacist before taking Zofran tablets.

Other medicines and Zofran

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken or might take other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Zofran can affect the way some medicines work. Also some other medicines can affect the way Zofran works.

In particular, tell your doctor, nurse or pharmacist if you are taking any of the following medicines:

- carbamazepine or phenytoin used to treat epilepsy
- rifampicin used to treat infections such as tuberculosis (TB)
- antibiotics such as erythromycin or ketoconazole
- anti-arrhythmic medicines used to treat an uneven heart beat
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines
- tramadol, a pain killer
- 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
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine, duloxetine.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before having Zofran tablets.

Pregnancy and breast-feeding

Only use during the first trimester of pregnancy after discussion with your doctor of the potential benefits and risks to you and your unborn baby of the different treatment options. This is because Zofran can slightly increase the risk of a baby being born with cleft lip and/or cleft palate (openings or splits in the upper lip and/or the roof of the mouth). If you are already pregnant, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Zofran. If you are a woman of childbearing potential you may be advised to use effective contraception.

Do not breast-feed if you are taking Zofran. This is because small amounts pass into the mother's milk. Ask your doctor or midwife for advice.

Important information about some of the ingredients of Zofran tablets

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, speak to your doctor before taking this medicine.

3. HOW TO TAKE ZOFRAN TABLETS

Always take Zofran tablets exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure. The dose you have been prescribed will depend on the treatment you are having.

To prevent nausea and vomiting from chemotherapy or radiotherapy

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 twelve hours after.

On the following days

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

Children aged over 6 months and adolescents

The doctor will decide the dose depending on the child's size (body surface area) or weight. Look at the label for more information.

- the usual dose for a child is up to 4 mg twice a day
- this can be given for up to 5 days.

To prevent nausea and vomiting after an operation

The usual adult dose is 16 mg before your operation

Children aged over 1 month and adolescents:

It is recommended that Zofran is given as an injection.

Patients with moderate or severe liver problems

The total daily dose should not be more than 8 mg.

Zofran tablets should start to work within one or two hours of taking a 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 label says.
- If you continue to feel sick, tell your doctor or nurse.

If you take more Zofran tablets than you should

If you or your child take more Zofran than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Zofran tablets

If you miss a dose **and** feel sick or vomit:

- take Zofran tablets as soon as possible, then
- take your next tablet at the usual time (as shown on the label)
- do not take a double dose to make up for a forgotten dose.

If you miss a dose but do not feel sick

- take the next dose as shown on the label
- do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

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

Allergic reactions

If you have an allergic reaction, stop taking it and see a doctor straight away. The signs may include:

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

Other side effects include:**Very common (may affect more than 1 in 10 people)**

- headache.

Common (may affect 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 affect up to 1 in 100 people)

- hiccups
- low blood pressure, which can make you feel faint or dizzy
- uneven heart beat
- chest pain
- fits
- unusual body movements or shaking.

Rare (may affect up to 1 in 1,000 people)

- feeling dizzy or light headed
- blurred vision
- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)

Very rare (may affect up to 1 in 10,000 people)

- poor vision or temporary loss of eyesight, which usually comes back within 20 minutes.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE ZOFRAN TABLETS

Keep out of the sight and reach of children.

A child may be harmed by medicine prescribed for someone else.

Do not store above 30°C. Store in the original package.

Do not use the tablets after the expiry date printed on the carton.

If your doctor tells you to stop taking Zofran tablets, it is important to return any which are left over to your pharmacist.

If your tablets become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Zofran tablets contain**

Zofran 4mg Tablets contain 4mg ondansetron (as hydrochloride dihydrate) as active ingredient.

Zofran 8mg Tablets contain 8mg ondansetron (as hydrochloride dihydrate) as active ingredient.

Other inactive ingredients: lactose, pregelatinised maize starch, microcrystalline cellulose, magnesium stearate, hypromellose and opaspray M-1-8429 yellow.

What Zofran tablets look like and contents of the pack

Zofran 4mg Tablets are oval yellow film coated tablets marked 'Glaxo' on one face and "4" on the other.

Zofran 8mg Tablets are oval yellow film coated tablets marked as 'Glaxo' on one face and "8" on the other.

Zofran is available in blister strip packs of 10 tablets.

MANUFACTURER AND PRODUCT LICENCE HOLDER

Manufactured by GlaxoSmithKline Pharmaceuticals S.A., ul. Grunwaldzka 189, 60-322 Poznan, Poland. Procured from within the EU by Product Licence holder: Tenolol Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

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