Patient Information Leaflet for

ZOFER® INJECTION

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ZOFER® 4 mg INJECTION

ZOFER® 8 mg INJECTION

Ondansetron

Sugar free

Read all of this leaflet carefully before you receive ZOFER INJECTION:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet:

Signed:

1. What ZOFER INJECTION is and what it is used for

ZOFER contains ondansetron, which belongs to a group of medicines called anti-emetics.

ZOFER is indicated for the treatment of nausea and vomiting caused by cancer chemotherapy and radiotherapy.

ZOFER is also indicated for the prevention and treatment of nausea and vomiting after an operation. This should not be recommended for patients in whom there is little expectation that nausea and vomiting will occur.

2. What you need to know before ZOFER INJECTION is administered

ZOFER INJECTION should not be administered to you:

- If you are hypersensitive (allergic) to ondansetron or any of the other ingredients of ZOFER (listed in section 6).
- During the first 12 weeks of your pregnancy (see section 2 “Pregnancy and breastfeeding”).
- To treat nausea and vomiting after having an operation while you are pregnant (see section 2 “Pregnancy and breastfeeding”).
- If you are taking apomorphine (used to treat Parkinson’s disease).
- If you have an inherited heart rhythm disorder (known as long QT syndrome).

Warnings and precautions:

Tell your doctor or health care provider before being administered the injection:

- If you are hypersensitive to other selective 5-HT_3 receptor antagonists.
- If you have ever had heart problems (such as congestive heart failure, which cause shortness of breath and swollen ankles).
- If you have an uneven heartbeat (dysrhythmia).
- If you are taking other medicines which affect your heart rhythm and lead to QT prolongation (see section 2, “Other medicines and ZOFER”).
- If you experience sudden chest pain or chest tightness (myocardial ischemia.
- If you have problems with the level of salts in your blood, such as potassium, sodium and magnesium.
- If you have liver impairment (moderate or severe), the total daily dose of 8 mg should not be exceeded.
- If you have intestinal obstructions (constipation) you should be monitored very carefully after using ZOFER.
- If you have to undergo adenotonsillar surgery (removal of tonsils and adenoids which are located at the back of the nasal cavity). The prevention of nausea and vomiting with ZOFER may hide bleeding that occurs in an area that is not visible.

Children and adolescents:

The daily dose for children should not be more than 4 mg.

Paediatric patients receiving ondansetron with chemotherapeutic medicines that cause toxic effects of the liver, should be closely monitored for weakened liver function.

Other medicines and ZOFER INJECTION:

Always tell your health care provider if you are taking any other medicines. (This includes complementary or traditional medicines.)

Do not use ZOFER together with apomorphine (used to treat Parkinson's disease) (see section 2, "ZOFER should not be administered to you").

Tell your doctor if you are using:

- Carbamazepine or phenytoin (used to treat epilepsy).
- Rifampicin (used to treat infections such as tuberculosis/TB).
- Antibiotics such as erythromycin or ketoconazole.
- Amiodarone or other antidysrhythmic medicines (used to treat an uneven heartbeat).
- Beta blocker medicines such as atenolol and timolol (used to treat certain heart or eye problems, anxiety or to prevent migraines).
- Tramadol (a painkiller).
- 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.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving ZOFER.

You should not receive ZOFER during the first 12 weeks of your pregnancy, as ZOFER may cause an opening or split (cleft) in the roof of the mouth or the upper lip of the fetus.

You should not receive ZOFER for treating nausea and vomiting following an operation if you are pregnant.

If you are a woman of childbearing potential, you should consider the use of effective contraception while taking ZOFER, as well as for two days after stopping treatment with ZOFER.

ZOFER should not be used during breastfeeding. This is because small amounts pass into the mother's milk.

Driving and using machines:

ZOFER may affect your ability to drive and use machines. You should use caution when driving or using machinery, until the effect of ZOFER is known.

ZOFER INJECTION contains sodium:

ZOFER INJECTION contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially sodium-free.

3. How ZOFER INJECTION will be administered

You will not be expected to give yourself ZOFER INJECTION. It will be given to you by a person who is qualified to do so.

Your doctor will decide the dose of ZOFER INJECTION, which will depend on the treatment you are having.

ZOFER INJECTION will be given by a slow injection into your vein or an injection into your muscle.

If you have the impression that the effect of ZOFER INJECTION is too strong or too weak, tell your doctor or pharmacist.

If you receive more ZOFER INJECTION than you should:

Since a health care provider will administer ZOFER INJECTION, he/she will control the dosage. However, in the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms include severe constipation, visual disturbances, low blood pressure and heartbeat irregularities. There is no specific antidote for ondansetron.

If you forget to receive ZOFER INJECTION:

Since a health care provider will administer ZOFER INJECTION, it is unlikely that the dose will be missed. If you think that you may have missed a dose, talk to your doctor or health care provider.

4. Possible side effects

ZOFER can have side effects.

Not all side effects reported for ZOFER are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ZOFER, please consult your health care provider for advice.

If any of the following happens, stop receiving ZOFER and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips and mouth or throat which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZOFER. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Seizures (convulsions or fits).
- Sudden chest pain or chest tightness.
- Irregular or accelerated heartbeat or low blood pressure.
- Abnormal or disturbance in your heart rhythm (which sometimes can cause a sudden loss of consciousness).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache.
- Visual disturbances such as blurred vision.
- A sensation of warmth or flushing.
- Constipation.

Less frequent side effects:

- Involuntary movements of muscles.
- Hiccups.
- Dizziness.
- Poor vision or temporary loss of eyesight, which usually comes back within 20 minutes.
- Changes to liver function test results (if you take ZOFER with a medicine called cisplatin, otherwise this side effect is uncommon).

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

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ZOFER.

Signed:

5. How to store ZOFER

Store at or below 25°C. Protect from light. Do not refrigerate.

Do not use after the expiry date printed on the outer container and ampoule.

KEEP OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ZOFER INJECTION contains:

The active substance is ondansetron (as ondansetron hydrochloride):

ZOFER 4 mg INJECTION: Each ampoule contains 4 mg ondansetron (as hydrochloride) in 2 mL aqueous solution.

ZOFER 8 mg INJECTION: Each ampoule contains 8 mg ondansetron (as hydrochloride) in 4 mL aqueous solution.

The other ingredients are:

ZOFER 4 mg and 8 mg INJECTION: Citric acid (monohydrate), sodium chloride, sodium citrate (dihydrate), water for injection.

What ZOFER INJECTION looks like and contents of the pack:

Colourless solution.

Contents of the pack:

ZOFER 4 mg INJECTION: 2 mL clear glass ampoules with a violet dot.

ZOFER 8 mg INJECTION: 5 mL clear glass ampoules with a grey dot.

Pack size: Five ampoules are packed in a plastic tray, in an outer carton.

Not all pack sizes may be marketed.

Holder of certificate of registration:

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill, Ext. 1, Roodepoort

Johannesburg 1724

011 495 0100

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21 May 2025

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ZOFER® 8 mg INJECTION: A39/5.10/0449

Date of registration:

25 November 2005

Namibia registration details:

Scheduling status: NS2

ZOFER®4 mg INJECTION: 06/5.10/0328

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Signed: