Patient Information Leaflet for

ZOFER® TABLETS/RAPITABS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ZOFER® 4 mg TABLETS film-coated tablet

ZOFER® 8 mg TABLETS film-coated tablet

ZOFER® RAPITAB 4 dispersible tablet

ZOFER® RAPITAB 8 dispersible tablet

Ondansetron

ZOFER 4 mg TABLETS contains sugar (99,35 mg lactose per film-coated tablet).

ZOFER 8 mg TABLETS contains sugar (198,7 mg lactose per film-coated tablet).

ZOFER RAPITAB 4 contains sugar alcohol (104,4 mg mannitol) and sweetener (3,9 mg aspartame) per dispersible tablet.

ZOFER RAPITAB 8 contains sugar alcohol (208,8 mg mannitol) and sweetener (7,8 mg aspartame).

Read all of this leaflet carefully before you start taking ZOFER:

- Keep this leaflet. You may need to read it again.

Signed:

- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ZOFER has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What ZOFER 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 you take ZOFER

Do not take ZOFER:

- 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:

Take special care with ZOFER:

- 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:

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, "Do not take ZOFER").

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 using ZOFER.

Do not use 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.

Do not use 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 TABLETS contains lactose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ZOFER TABLETS.

ZOFER RAPITAB contains aspartame:

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take ZOFER

Do not share medicines prescribed for you with any other person.

Always take ZOFER exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

ZOFER is for oral use only.

ZOFER TABLETS are to be swallowed whole.

ZOFER RAPITABS are to be placed under tongue.

The usual dose is:

Adult dose:

Treatment to help against nausea and vomiting induced by cancer chemotherapy and radiotherapy:

- Initial: 8 mg tablet one to two hours before treatment, followed by 8 mg orally twelve hourly.
- In circumstances where delayed or prolonged emesis is expected after the first 24 hours, ZOFER may be continued orally, 8 mg twice daily for up to five days after a course of treatment.

Treatment to help against post-operative nausea and vomiting:

- For the prevention of post-operative nausea and vomiting, 16 mg may be given orally (film-coated tablets) one hour prior to induction of anaesthesia.

Paediatric dose:

Treatment to help against nausea and vomiting induced by cancer chemotherapy and radiotherapy:

Children 4 years and older: Injection treatment can be followed by oral therapy of doses of ZOFER 4 mg every 12 hours for up to 5 days.

Treatment to help against post-operative nausea and vomiting:

A dosage has not been established.

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

If you take more ZOFER than you should:

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 take ZOFER:

If you forgot to take a dose of ZOFER, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the next tablet at the usual time.

Do not take a double dose of ZOFER to make up for forgotten individual doses.

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 using 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 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.

- Poor vision or temporary loss of eyesight, which usually comes back within 20 minutes.
- Changes to liver function test results (if you take ZOFER tablets 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ZOFER.

5. How to store ZOFER

Store at or below 25 °C.

Protect from light and moisture.

Keep blister strip in outer carton until required for use.

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

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ZOFER contains:

The active substance is ondansetron (as ondansetron hydrochloride):

ZOFER 4 mg TABLETS: Each film-coated tablet contains ondansetron hydrochloride equivalent to 4 mg ondansetron.

ZOFER 8 mg TABLETS: Each film-coated tablet contains ondansetron hydrochloride equivalent to 8 mg ondansetron.

ZOFER RAPITAB 4: Each dispersible tablet contains ondansetron hydrochloride equivalent to 4 mg ondansetron.

ZOFER RAPITAB 8: Each dispersible tablet contains ondansetron hydrochloride equivalent to 8 mg ondansetron.

The other ingredients are:

ZOFER 4 mg and 8 mg TABLETS: Lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, pregelatinised starch.

ZOFER 4 mg TABLETS: Opadry White, containing hypromellose, polyethylene glycol 400 and titanium dioxide (C.I.77892).

ZOFER 8 mg TABLETS: Opadry Yellow, containing hypromellose, iron oxide yellow (Cl 77492), polyethylene glycol 400, polysorbate 80 and titanium dioxide (C.I.77891)).

ZOFER RAPITAB 4 and 8: Aspartame, colloidal silicon dioxide, croscarmellose sodium, glyceryl distearate, magnesium stearate, mannitol, strawberry flavoured powder (052312 AP 0551), purified talc.

What ZOFER looks like and contents of the pack:

ZOFER 4 mg TABLETS: White, oval shaped, film-coated tablets debossed with "130" on one side and plain on the other side.

ZOFER 8 mg TABLETS: Yellow, oval shaped, film-coated tablets debossed with "131" on one side and plain on the other.

ZOFER RAPITAB 4: White to off-white, oval shaped, uncoated tablets debossed with "240" on one side and plain on the other side.

ZOFER RAPITAB 8: White to off-white, oval shaped, uncoated tablets debossed with "241" on one side and plain on the other side.

Contents of the pack:

ZOFER 4 mg and 8 mg TABLETS: PVDC/PVC and aluminium blister strip.

Pack size: 1 blister strip contains 10 tablets, packed in an outer carton.

Contents of the pack:

ZOFER RAPITAB 4 and 8: White PVDC/PVC and aluminium blister strip.

Pack size: 1 blister strip contains 10 tablets, packed 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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ZOFER® 4 mg TABLETS: A39/5.10/0413

ZOFER® 8 mg TABLETS: A39/5.10/0414

ZOFER® RAPITAB 4: 42/5.10/0662

ZOFER® RAPITAB 8: 42/5.10/0663

Date of registration:

ZOFER 4 mg and 8 mg TABLETS: 25 November 2005

ZOFER RAPITAB 4 and 8: 09 October 2009

Namibia registration details:

Scheduling status: NS2

ZOFER® 4 mg TABLETS: 06/5.10/0330

ZOFER® 8 mg TABLETS: 06/5.10/0331

ZOFER® RAPITAB 4: 13/5.10/0032

ZOFER® RAPITAB 8: 13/5.10/0033

Signed: