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:

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

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

Signed:

3. How ZOFER INJECTION is administered

4. Possible side effects

5. How to store ZOFER INJECTION

6. Contents of the pack and other information.

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

This leaflet was last revised:

21 May 2025

Registration numbers:

ZOFER® 4 mg INJECTION: A39/5.10/0448

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

ZOFER® 8 mg INJECTION: 06/5.10/0329

Signed:

Patient Information Leaflet for ZOFER®
INJECTION

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

ZOFER® 4 mg INJECTION

ZOFER® 8 mg INJECTION

Ondansetron

Suikervry

Lees die hele inligtingsblad noukeurig deur voordat ZOFER INJECTION aan jou toegedien word:

- Hou hierdie inligtingsblad. Dit is moontlik dat jy dit weer sal wil lees.
- Indien jy verdere vrae het, raadpleeg asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.

Wat is in hierdie inligtingsblad:

1. Wat is ZOFER INJECTION en waarvoor word dit gebruik

Signed:

2. Wat jy moet weet voordat ZOFER INJECTION aan jou toegedien word

3. Hoe ZOFER INJECTION toegedien word

4. Moontlike newe-effekte

5. Hoe om ZOFER INJECTION te bewaar

6. Inhoud van die verpakking en ander inligting.

1. Wat is ZOFER INJECTION en waarvoor word dit gebruik

ZOFER bevat ondansetron, wat aan ‘n groep medisyne behoort wat bekend staan as anti-emetika. ZOFER is aangedui vir die behandeling van naarheid en braking veroorsaak deur kanker chemoterapie en bestralingsterapie.

ZOFER is ook aangedui vir die voorkoming en behandeling van naarheid en braking ná ‘n operasie. Dit word nie aanbeveel by pasiënte waar daar min verwagting is dat naarheid en braking sal voorkom.

2. Wat jy moet weet voordat ZOFER INJECTION aan jou toegedien word

ZOFER INJECTION moenie aan jou toegedien word nie:

- As jy hipersensitief (allergies) is vir ondansetron of enige van die ander bestanddele in ZOFER (gelys in afdeling 6).
- Tydens die eerste 12 weke van jou swangerskap (sien afdeling 2, “Swangerskap en borsvoeding”).

Signed:

- Om naarheid en braking te behandel nadat jy ‘n operasie ondergaan het terwyl jy swanger is (sien afdeling 2, “Swangerskap en borsvoeding”).
- As jy apomorfien neem (gebruik om Parkinson se siekte te behandel).
- As jy ‘n oorerflike hartritme-versteuring het (bekend as lang-QT-sindroom).

Waarskuwings en voorsorgmaatreëls:

Lig jou dokter of gesondheidsorgverskaffer in voordat die inspuiting aan jou toegedien word:

- As jy hipersensitief is vir ander selektiewe 5-HT_3 reseptor-antagoniste.
- As jy al ooit hartprobleme gehad het (soos kongestiewe hartversaking, wat kortasemigheid en geswelde enkels kan veroorsaak).
- As jy ‘n onreëlmatige hartklop het (disritmie).
- As jy ander medisyne gebruik wat jou hartritme affekteer en lei tot QT-verlenging (sien afdeling 2, “Ander medisyne en ZOFER”).
- As jy skielike borskaspyn of benoudheid in die borskas ervaar (miokardiale iskemie).
- As jy probleme het met die soutvlakke in jou bloed, soos kalium, natrium en magnesium.
- As jy lewerontoereikendheid het (matig of ernstig), moet die totale daaglikse dosis van 8 mg nie oorskry word nie.
- As jy intestinale obstruksie (hardlywigheid) het, moet jy baie noukeurig gemonitor word nadat jy ZOFER ontvang het.
- As jy adenotonsillêre chirurgie moet ondergaan (verwydering van mangels en adenoïede wat

aan die agterkant van die neusholte geleë is). Die voorkoming van naarheid en braking met ZOFER kan bloeding verberg wat voorkom in ‘n area wat nie sigbaar is nie.

Kinders en adolessente:

Die daaglikse dosis by kinders moet nie meer as 4 mg wees nie.

Pediatriese pasiënte wat ondansetron saam met chemoterapeutiese medisyne ontvang wat toksiese effekte van die lewer veroorsaak, moet noukeurig gemonitor word vir verswakte lewerfunksie.

Ander medisyne en ZOFER INJECTION:

Lig jou gesondheidsorgverskaffer altyd in as jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in.)

Moenie ZOFER saam met apomorfien (gebruik om Parkinson se siekte te behandel) gebruik nie (sien afdeling 2, “ZOFER moet nie aan jou toegedien word nie”).

Lig jou dokter in as jy die volgende gebruik:

- Karbamasepien of fenitoïen (gebruik om epilepsie te behandel).
- Rifampisien (gebruik vir die behandeling van infeksie soos tuberkulose/TB).
- Antibiotika, soos eritromisien of ketokonasool.
- Amiodaroon of ander antidisritmiese medisyne (gebruik om onreëlmatige hartklop te behandel).
- Beta-blokker medisyne soos atenolol en timolol (gebruik om sekere hart of oogprobleme, angstigheid te behandel of om migraine te voorkom).

Signed:

- Tramadol ('n pynstiller).
- Kankermedisyne (veral antrasikliene en trastuzumab).
- SSRIs (selektiewe serotonien-heropname-inhibeerders) gebruik om depressie en/of angstigheid te behandel, insluitend fluoksetien, paroksetien, sertralien, fluvoksamien, sitalopram, esitalopram.
- SNRIs (serotonien-noradrenalien-heropname-inhibeerders) gebruik om depressie en/of angstigheid te behandel, insluitend venlafaksien, duloksetien.

Swangerskap en borsvoeding:

As jy swanger is of borsvoed, dink dat jy swanger mag wees of as jy beplan om swanger te raak, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg vir advies voordat ZOFER aan jou toegedien word.

Jy moenie gedurende die eerste 12 weke van jou swangerskap ZOFER ontvang nie, aangesien ZOFER 'n opening of spleet (bars) in die verhemelte van die mond of in die bolip van die fetus kan veroorsaak.

Jy moenie ZOFER vir die behandeling van naarheid of braking na 'n operasie ontvang as jy swanger is nie.

As jy 'n vrou is van 'n ouderdom wat kinders kan baar, moet die die gebruik van doeltreffende voorbehoeding oorweeg word terwyl jy ZOFER ontvang, asook vir twee dae nadat behandeling met ZOFER gestaak is.

ZOFER moet nie tydens borsvoeding gebruik word nie. Dit is omdat klein hoeveelhede in die borsmelk uitgeskei word.

Bestuur en gebruik van masjinerie:

ZOFER kan die vermoë om te bestuur en masjinerie te gebruik beïnvloed. Jy moet versigtigheid toepas wanneer jy bestuur of masjinerie gebruik totdat die effek van ZOFER bekend is.

ZOFER INJECTION bevat natrium:

ZOFER INJECTION bevat minder as 1 mmol natrium (23 mg) per eenheidsdosis, daarom is dit feitlik natriumvry.

3. Hoe ZOFER INJECTION toegedien sal word

Daar sal nie van jou verwag word om ZOFER INJECTION aan jouself toe te dien nie. Dit sal aan jou gegee word deur 'n persoon wat opgelei is om dit te doen.

Jou dokter sal besluit oor die dosis van ZOFER INJECTION, wat sal afhang van die behandeling wat jy ontvang.

ZOFER INJECTION sal deur ‘n stadige inspuiting binne-in jou aar toegedien word of as ‘n inspuiting binne-in jou spier.

As jy onder die indruk is dat die effek van ZOFER INJECTION te sterk of te swak is, moet jy jou dokter of apteker inlig.

As jy meer ZOFER INJECTION ontvang het as wat jy behoort te ontvang:

Aangesien die gesondheidsorgverskaffer ZOFER INJECTION sal toedien, sal hy/sy die dosis kontroleer. In die geval van oordosering, moet jy egter jou dokter of apteker raadpleeg. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Simptome sluit erge hardlywigheid, visuele versteurings, lae bloeddruk en onreëlmatige hartklop in. Daar is geen spesifieke teenmiddel vir ondansetron nie.

As jy vergeet het om ZOFER INJECTION te ontvang:

Aangesien die gesondheidsorgverskaffer ZOFER INJECTION sal toedien, is dit onwaarskynlik dat die dosis oorgeslaan sal word. Praat met jou dokter of gesondheidsorgverskaffer as jy dink dat jy ‘n dosis oorgeslaan het.

4. Moontlike newe-effekte

ZOFER kan newe-effekte hê.

Nie alle newe-effekte wat vir ZOFER aangemeld word, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl jy ZOFER neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om ZOFER te ontvang en lig jou dokter dadelik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal:

- Swelling van jou hande, voete, enkels, gesig, lippe en mond of keel wat moeilike sluk of asemhaling kan veroorsaak.

- Uitslag of gejeuk.
- Floute.

Hierdie is almal baie ernstige newe-effekte. Indien jy dit ervaar, kon jy moontlik ‘n ernstige allergiese reaksie teenoor ZOFER gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Lig jou dokter dadelik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- Toevalle (konvulsies of aanvalle).
- Skielike borskaspyn of benoudheid in die borskas.
- Onreëlmatige of versnelde hartklop of lae bloeddruk.
- Abnormale of versteurings in jou hartritme (wat somtyd ‘n skielike verlies van bewussyn kan veroorsaak).

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese bystand benodig.

Lig jou dokter in as jy enige van die volgende opmerk:

Dikwelse newe-effekte:

- Hoofpyn.
- Visuele vertseurings soos belemmerde visie.
- ‘n Sensasie van hitte of blosing.
- Hardlywigheid.

Signed:
Signed:

Minder dikwelse newe-effekte

- Onwillekeurige spierbewegings.
- Hik.
- Duiseligheid.
- Swak sig of tydelike verlies aan sig, wat gewoonlik binne 20-minute terugkeer.
- Veranderinge aan toetsresultate vir lewerfunksie (as jy ZOFER saam met 'n medisyne neem wat bekend staan as sisplatien, andersins is hierdie newe-effek ongewoon)

Indien jy enige newe-effekte ondervind wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte:

Praat met jou dokter of apteker as jy newe-effekte ervaar. Jy kan ook newe-effekte by SAHPRA *via* die "**Adverse Drug Reaction Reporting Form**" aanmeld, wat aanlyn beskikbaar is onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van ZOFER te verskaf.

5. Hoe om ZOFER te bewaar

Bewaar by of onder 25 °C. Beskerm teen lig. Moenie in die yskas bêre nie.

Moenie ná die vervaldatum, soos op die buitenste karton en ampule aangedui, gebruik nie.

HOU BUITE DIE BEREIK VAN KINDERS.

Bring alle ongebruikte medisyne terug na jou apteker toe.

Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

Signed:

6. Inhoud van die verpakking en ander inligting

Wat ZOFER INJECTION bevat:

Die aktiewe bestanddeel is ondansetron (as ondansetronhidrochloried):

ZOFER 4 mg INJECTION: Elke ampule bevat 4 mg ondansetron (as hidrochloried) in 2 mL waterige oplossing.

ZOFER 8 mg INJECTION: Elke ampule bevat 8 mg ondansetron (as hidrochloried) in 4 mL waterige oplossing.

Die ander bestanddele is:

ZOFER 4 mg en 8 mg INJECTION: Sitroensuur (monohidraat), natriumchloried, natriumsitraat (dihidraat), water vir inspuiting.

Hoe ZOFER INJECTION lyk en inhoud van die pakkie:

Kleurlose oplossing.

Inhoud van die pakkie:

ZOFER 4 mg INJECTION: 2 mL kleurlose glasampules met ‘n pers kolletjie.

ZOFER 8 mg INJECTION: 5 mL kleurlose glasampules met ‘n grys kolletjie.

Pakgrootte: Vyf ampules word verpak in ‘n plastiekbakkie, in ‘n buitenste karton.

Houer van die registrasiesertifikaat:

Ranbaxy Pharmaceuticals (Pty) Ltd

Lautreweg 14

Stormill, Uitbreiding 1, Roodepoort

Johannesburg 1724

011 495 0100

Hierdie inligtingstuk was laas hersien op:

21 Mei 2025

Registrasienommers:

ZOFER® 4 mg INJECTION: A39/5.10/0448

ZOFER® 8 mg INJECTION: A39/5.10/0449

Datum van registrasie:

25 November 2005

Namibië se registrasiebesonderhede:

Skeduleringstatus: NS2

ZOFER®4 mg INJECTION: 06/5.10/0328

ZOFER® 8 mg INJECTION: 06/5.10/0329

Signed: