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
2. What you need to know before you take ZOFER
3. How to take ZOFER
4. Possible side effects
5. How to store ZOFER
6. Contents of the pack and other information.

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

This leaflet was last revised:

21 May 2025

Registration numbers:

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:

Patient Information Leaflet for

ZOFER® TABLETS/RAPITABS

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

ZOFER® 4 mg TABLETS filmbedekte tablet

ZOFER® 8 mg TABLETS filmbedekte tablet

ZOFER® RAPITAB 4 oplosbare tablet

ZOFER® RAPITAB 8 oplosbare tablet

Ondansetron

ZOFER 4 mg TABLETS bevat suiker (99,35 mg laktose per filmbedekte tablet).

ZOFER 8 mg TABLETS bevat suiker (198,7 mg laktose per filmbedekte tablet).

ZOFER RAPITAB 4 bevat suikeralkohol (104,4 mg mannitol) en versoeter (3,9 mg aspartaam) per dispersible tablet.

ZOFER RAPITAB 8 bevat suikeralkohol (208,8 mg mannitol) en versoeter (7,8 mg aspartaam) per dispersible tablet.

Lees die hele inligtingsblad noukeurig deur voordat jy begin om ZOFER te neem:

- Hou hierdie inligtingsblad. Dit mag vir jou nodig wees om dit weer te lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vir advies as jy enige verdere vrae het.

Signed: _____

- ZOFER is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met enige ander persoon deel nie. Dit kan skadelik vir hulle wees, selfs as hulle simptome dieselfde as joune is.

Wat is in hierdie inligtingsblad:

1. Wat ZOFER is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy ZOFER gebruik
3. Hoe om ZOFER te gebruik
4. Moontlike newe-effekte
5. Hoe om ZOFER te bewaar
6. Inhoud van die verpakking en ander inligting.

1. Wat ZOFER is en waarvoor dit gebruik word

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

2. Wat jy moet weet voordat jy ZOFER gebruik

Moenie ZOFER gebruik nie:

- As jy hipersensitief (allergies) is vir ondansetron of enige van die ander bestanddele in ZOFER (gelys in afdeling 6).

Signed:

- Gedurende die eerste 12 weke van jou swangerskap (sien afdeling 2, “Swangerskap en borsvoeding”)
- 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:

Tref spesiale voorsorg met ZOFER:

- 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 geneem 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:

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, " Moenie ZOFER neem 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).
- 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, vermoed 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 jy ZOFER neem.

Jy moenie gedurende die eerste 12 weke van jou swangerskap ZOFER neem 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 jy die gebruik van doeltreffende voorbehoeding oorweeg terwyl jy ZOFER neem, 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 TABLETS bevat laktose:

As jou dokter vir jou gesê het dat jy ‘n onverdraagsaamheid teenoor sekere suikers het, moet jy jou dokter kontak voordat jy ZOFER neem.

Signed:

ZOFER RAPITAB bevat aspartaam:

Aspartaam is ‘n bron van fenielalanien. Dit kan skadelik wees as jy fenielketonurie het, ‘n seldsame genetiese versteuring waarin die fenielalanien ophoop omdat die liggaam dit nie behoorlik kan verwyder nie.

3. Hoe om ZOFER te gebruik

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem ZOFER altyd presies soos wat jou dokter of apteker dit voorgeskryf het. Kontroleer met jou dokter of apteker as jy nie seker is nie.

ZOFER is slegs vir orale gebruik.

ZOFER TABLETS moet heel ingesluk word.

ZOFER RAPITABS moet onder die tong geplaas word.

Die normale dosis is:

Volwasse dosis:

Behandeling om te help met naarheid en braking wat deur kanker-chemoterapie en bestralingsterapie geïnduseer word:

- Aanvanklik: 8 mg tablet een of twee uur vóór behandeling, gevolg deur 8 mg twaalf-uurliks mondeliks geneem.
- In omstandighede waar vertraagde of verlengde emese ná die eerste 24 uur verwag word, kan met ZOFER mondeliks voortgegaan word, 8 mg twee keer per dag vir tot vyf dae ná die behandelingskursus.

Behandeling om te help teen post-operatiewe naarheid en braking:

- Vir die voorkoming van post-operatiewe naarheid en braking, kan 16 mg (filmbedekte tablette)

mondeliks geneem word een uur vóór induksie van narkose.

Pediatriese dosis:

Behandeling om te help met naarheid en braking wat deur kanker-chemoterapie en bestralingsterapie geïnduseer word:

Kinders 4 jaar en ouer: Inspuitingsbehandeling kan opgevolg word deur mondelikse terapie met dosisse van 4 mg ZOFER elke 12 uur vir tot 5 dae.

Behandeling om te help teen post-operatiewe naarheid en braking:

'n Dosering is nog nie vasgestel nie.

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

As jy meer ZOFER geneem het as wat jy behoort te neem:

In die geval van oordosering, moet jy 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 te neem:

As jy vergeet het om 'n dosis ZOFER te neem, neem dit so gou as wat jy onthou. As dit amper tyd is vir jou volgende dosis, slaan die dosis oor wat jy vergeet het en neem jou volgende tablet op die gewone tyd.

Moenie ‘n dubbele dosis ZOFER neem om te vergoed vir die individuele dosisse wat jy vergeet het nie.

4. Moontlike newe-effekte

ZOFER kan newe-effekte hê.

Nie alle newe-effekte wat vir ZOFER aangemeld word, is in 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 neem 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 8ospital 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 versteurings soos belemmerde visie.
- ‘n Sensasie van hitte of blosing.
- Hardlywigheid

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 tablette 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 aanmeld *via* die Med Safety APP (Medsafety X SAHPRA) en eReporting-platform (who-umc.org) wat aanlyn beskikbaar is onder SAHPRA se webtuiste. 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 en vog.

Hou die stulpstrook in die buitenste karton tot benodig vir gebruik.

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

HOU BUITE DIE BEREIK VAN KINDERS.

6. Inhoud van die verpakking en ander inligting

Wat ZOFER bevat:

Die aktiewe bestanddeel is ondansetron (as ondansetronhidrochloried):

ZOFER 4 mg TABLETS: Elke filmbedekte tablet bevat ondansetronhidrochloried gelykstaande aan 4 mg ondansetron.

ZOFER 8 mg TABLETS: Elke filmbedekte tablet bevat ondansetronhidrochloried gelykstaande aan 8 mg ondansetron.

ZOFER RAPITAB 4: Elke oplosbare tablet bevat ondansetronhidrochloried gelykstaande aan 4 mg ondansetron.

ZOFER RAPITAB 8: Elke oplosbare tablet bevat ondansetronhidrochloried gelykstaande aan 8 mg ondansetron.

Die ander bestanddele is:

ZOFER 4 mg en 8 mg TABLETS: Laktose, magnesiumstearaat, mikrokristallyne sellulose, poliëtileenglikool 400, voorafgegelatiniseerde stysel.

ZOFER 4 mg TABLETS: Opadry Wit, bevattende hipromellose, poliëtileenglikool 400 en titaandioksied (C.I.77892).

ZOFER 8 mg TABLETS: Opadry Geel, bevattende hipromellose, geel ysteroksied (Cl 77492), poliëtileenglikool 400, polisorbaat en titaandioksied (C.I.77891)).

ZOFER RAPITAB 4 en 8: Aspartaam, kolloïdale silikondioksied, natriumkroskarmellose, gliserieldistearaat, magnesiumstearaat, mannitol, aarbei-gegeurde poeier (052312 AP 0551), gesuiwerde talk.

Hoe ZOFER lyk en inhoud van die verpakking:

ZOFER 4 mg TABLETS: Wit, ovaalvormige, filmbedekte tablette ingepers met "130" op die een kant en skoon op die ander kant.

ZOFER 8 mg TABLETS: Geel, ovaalvormige, filmbedekte tablette ingepers met "131" op die een kant en skoon op die ander kant.

ZOFER RAPITAB 4: Wit tot naaswit, ovaalvormige, onbedekte tablette ingepers met "240" op die een kant en skoon op die ander kant.

ZOFER RAPITAB 8: Wit tot naaswit, ovaalvormige, onbedekte tablette ingepers met "241" op die een kant en skoon op die ander kant.

Inhoud van die verpakking:

ZOFER 4 mg en 8 mg TABLETS: PVDC/PVC en aluminium-stulpstrook.

Pakgrootte: 1 stulpstrook bevat 10 tablette, verpak in ‘n buitenste karton.

Inhoud van die verpakking:

ZOFER RAPITAB 4 en 8: Wit PVDC/PVC en aluminium-stulpstrook.

Pakgrootte: 1 stulpstrook bevat 10 tablette, verpak 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 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

Datum van registrasie:

ZOFER 4 mg en 8 mg TABLETS: 25 November 2005

ZOFER RAPITAB 4 en 8: 09 Oktober 2009

Toegang tot die ooreenstemmende Professionele Inligting

Namibië se registrasiebesonderhede:

Skeduleringstatus: 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: