Front Side

320 mm

ERAFLEX
25/50/100 MG
(film-coated tablet)
PM03984802

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

ERAFLEX 25 mg
Sildenafil Citrate equivalent to 25 mg Sildenafil
ERAFLEX 50 mg
Sildenafil Citrate equivalent to 50 mg Sildenafil
ERAFLEX 100 mg
Sildenafil Citrate equivalent to 100 mg Sildenafil
Sugar free

Read all of this leaflet carefully before you start taking ERAFLEX
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **ERAFLEX** 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 **ERAFLEX** is and what it is used for
2. What you need to know before you take **ERAFLEX**
3. How to take **ERAFLEX**
4. Possible side effects
5. How to store **ERAFLEX**
6. Contents of the pack and other information

1. What ERAFLEX is and what it is used for

ERAFLEX contains the active substance sildenafil which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors.
ERAFLEX works by relaxing the blood vessels in your penis when you are sexually excited. This allows blood to flow into your penis, allowing you to get an erection in the natural way.
ERAFLEX is used to treat erectile dysfunction, sometimes known as impotence, in men. This is when a man cannot get, or keep, a hard, erect penis suitable for sexual activity.
ERAFLEX will work only if you are sexually excited.
ERAFLEX will not increase your sex drive.
ERAFLEX is not for use in women.

2. What you need to know before you take ERAFLEX

Do not take ERAFLEX:
- If you are hypersensitive (allergic) to sildenafil or any of the other ingredients of **ERAFLEX** (listed in section 6).
- If you are taking medicines called nitrates, as the combination may lead to a dangerous fall in your blood pressure. Tell your doctor if you are taking any of these medicines which are often given for relief of angina pectoris (or "chest pain"). If you are not certain, ask your doctor or pharmacist.
- If you are using any of the medicines known as nitric oxide donors such as amyl nitrite ("poppers"), as the combination may also lead to a dangerous fall in your blood pressure.
- If you are taking riociguat. Riociguat is used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs secondary to blood clots). PDE5 inhibitors, such as **ERAFLEX** have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.
- If you are using cimetidine (used to treat ulcers), ketoconazole or itraconazole (used to treat fungal infections), erythromycin or rifampicin (used to treat infections) or ritonavir or saquinavir (used to treat HIV infections).
- If you have severe problems with your heart (such as unstable angina or heart failure).
- If you have ever had loss of vision due to non-arteritic anterior ischaemic optic neuropathy (NAION).
- If you have a severe kidney or liver problem.
- If you have recently had a stroke or a heart attack, or if you have low blood pressure.
- If you have certain rare inherited eye diseases (such as *retinitis pigmentosa*).

Warnings and precautions
Take special care with **ERAFLEX**:
- If you have problems with your heart. Your doctor should carefully check whether your heart can take the additional strain of having sex.
- If you have a deformity of your penis or Peyronie's Disease.
- If you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow).
- If you currently have a stomach ulcer, or a bleeding problem (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking **ERAFLEX** and contact your doctor immediately.

You should not use **ERAFLEX** with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitors.
You should not use **ERAFLEX** with any other oral or local treatments for erectile dysfunction.
You should not take **ERAFLEX** if you do not have erectile dysfunction.

Children and adolescents
ERAFLEX should not be given to individuals under the age of 18.

Other medicines and ERAFLEX
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
- **ERAFLEX** tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell your doctor, pharmacist or nurse that you have taken **ERAFLEX** and when you did. Do not take **ERAFLEX** with other medicines unless your doctor tells you that you can.
- You should not take **ERAFLEX** if you are taking medicines called nitrates, as the combination of these medicines may lead to a dangerous fall in your blood pressure. Always tell your doctor, pharmacist or nurse if you are taking any of these medicines that are often used for the relief of angina pectoris (or "chest pain").
- You should not take **ERAFLEX** if you are using any of the medicines known as nitric oxide donors such as amyl nitrite ("poppers") as the combination may also lead to a dangerous fall in your blood pressure.
- Tell your doctor or pharmacist if you are already taking riociguat.
- If you are taking medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25 mg) of **ERAFLEX**.
- Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking **ERAFLEX** with alpha-blockers. This is most likely to happen within 4 hours after taking **ERAFLEX**. In order to reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start **ERAFLEX**. Your doctor may start you on a lower dose (25 mg) of **ERAFLEX**.

ERAFLEX with food and drink
ERAFLEX can be taken with or without food. However, you may find that **ERAFLEX** takes longer to start working if you take it with a heavy meal.
Drinking alcohol can temporarily impair your ability to get an erection. To get the maximum benefit from your medicine, you are advised not to drink excessive amounts of alcohol before taking **ERAFLEX**.

Pregnancy, breastfeeding and fertility
ERAFLEX is not indicated for use in women.

Driving and using machines
ERAFLEX can cause dizziness and can affect vision. You should be aware of how you react to **ERAFLEX** before you drive or use machinery.

3. How to take ERAFLEX

Do not share medicines prescribed for you with any other person.
Always take **ERAFLEX** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The usual dose is 50 mg, taken about one hour before sexual activity. This dose may be increased to 100 mg or decreased to 25 mg by your doctor. Swallow the tablet whole with some water.
ERAFLEX will only help you to get an erection if you are sexually stimulated. The amount of time **ERAFLEX** takes to work varies from person to person, but it normally takes between half an hour and one hour.
If **ERAFLEX** does not help you to get an erection or if your erection does not last long enough for you to complete sexual intercourse you should tell your doctor. You should not use **ERAFLEX** more than once a day.
If you have the impression that the effect of **ERAFLEX** is too strong or too weak, tell your doctor or pharmacist.
If you take more ERAFLEX than you should
Taking a dose higher than 100 mg does not increase the effect of **ERAFLEX**. However, it will result in an increase in undesirable effects and their severity. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

4. Possible side effects

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

If any of the following happens, stop taking **ERAFLEX** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the 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 reaction to **ERAFLEX**. 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:
Less frequent
- chest pains,
- prolonged and sometimes painful erections,
- a sudden decrease or loss of vision,
- serious skin reactions (symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever),
- seizures or fits.

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

Tell your doctor if you notice any of the following:
Frequent
- headache, dizziness
- nausea, indigestion,
- facial flushing, hot flush,
- colour tinge to vision, blurred vision, visual disturbance,
- stuffy nose.

Less frequent
- vomiting,
- skin rash,
- eye irritation, bloodshot eyes/red eyes, eye pain, seeing flashes of light, visual brightness, light sensitivity, watery eyes,
- pounding heartbeat, rapid heartbeat, high blood pressure, low blood pressure,
- muscle pain,
- feeling sleepy, reduced sense of touch,
- vertigo, ringing in the ears,
- dry mouth,
- blocked or stuffy sinuses, inflammation of the lining of the nose, nosebleed,
- upper abdominal pain, gastro-oesophageal reflux disease (symptoms include heartburn),
- presence of blood in urine,
- pain in the arms or legs,
- feeling hot, feeling tired,
- fainting, stroke, heart attack, irregular heartbeat, temporary decreased blood flow to parts of the brain,
- feeling of tightening of the throat, numb mouth,
- bleeding at the back of the eye, double vision, reduced sharpness of vision, abnormal sensation in the eye, swelling of the eye or eyelid, small particles or spots in your vision, seeing halos around lights, dilation of the pupil of the eye, discolouration of the white of the eye,
- penile bleeding, presence of blood in semen,
- dry nose, swelling of the inside of the nose,
- feeling irritable,
- sudden decrease or loss of hearing.

Frequency unknown
- unstable angina (a heart condition),
- sudden death,
- retinal detachment (which may appear as tiny specks through your field of vision).

If you notice any side effects not mentioned in this 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 "6.04 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 **ERAFLEX**.

5. How to store ERAFLEX

Store at or below 25 °C.
Keep the blisters in the carton until required for use.
Keep HDPE containers tightly closed.
Store in the original package in order to protect from light and moisture.
KEEP OUT OF THE REACH OF CHILDREN.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / label / carton / bottle.
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 ERAFLEX contains
ERAFLEX 25 mg:
The active ingredient in **ERAFLEX 25 mg** is Sildenafil Citrate equivalent to 25 mg Sildenafil.

ERAFLEX 50 mg:
The active ingredient in **ERAFLEX 50 mg** is Sildenafil Citrate equivalent to 50 mg Sildenafil.

ERAFLEX 100 mg:
The active ingredient in **ERAFLEX 100 mg** is Sildenafil Citrate equivalent to 100 mg Sildenafil.
Other ingredients are:
Croscarmellose sodium, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose. Film coating including hypromellose, titanium dioxide, triacetin and FD & C blue # 2/Indigo Carmine aluminum Lake.

What ERAFLEX looks like and contents of the pack
ERAFLEX 25 mg
Blue coloured, diamond shaped, film coated tablets debossed with "CL 35" on one side and plain on the other side.

ERAFLEX 50 mg
Blue coloured, diamond shaped, film coated tablets debossed with "CL 36" on one side and plain on the other side.

ERAFLEX 100 mg
Blue coloured, diamond shaped, film coated tablets debossed with "CL 37" on one side and plain on the other side.

Content of the pack:
Blister Pack:
Aluminium foil of 6-8 gsm heat seal lacquered as the lidding material and clear PVC film coated with PVdC as the forming material.
Pack size include 1's, 2's, 4's, 8's, 10's and 12's tablets
Container Pack:
40 ml round white HDPE container with 33 - 400 neck finish closed with child resistant closure with pulp and heat seal liner.
Pack size 30 tablets
*Not all pack sizes will be marketed.

Holder of Certificate of Registration
Macleods Pharmaceuticals SA (Pty) Ltd
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

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Registration numbers
ERAFLEX 25 mg: 46/7.1.5/0254
ERAFLEX 50 mg: 46/7.1.5/0255
ERAFLEX 100 mg: 46/7.1.5/0256

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www. macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

335 mm

Back Side

320 mm

335 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

ERAFLEX 25 mg
Sildenafilsitraat gelykstaande aan 25 mg Sildenafil
ERAFLEX 50 mg
Sildenafilsitraat gelykstaande aan 50 mg Sildenafil
ERAFLEX 100 mg
Sildenafilsitraat gelykstaande aan 100 mg Sildenafil
Suikervry

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy ERAFLEX begin gebruik
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het
- **ERAFLEX** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

1. Wat **ERAFLEX** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **ERAFLEX** neem
3. Hoe om **ERAFLEX** te neem
4. Moontlike newe-effekte
5. Hoe om **ERAFLEX** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat ERAFLEX is en waarvoor dit gebruik word

ERAFLEX bevat die aktiewe bestanddeel sildenafil wat behoort aan 'n groep medisyne genaamd fosfodiësterase tipe 5 (PDE5) inhibeerders.
ERAFLEX werk deur die bloedvate in jou penis te laat ontspan wanneer jy seksueel opgewonde is. Dit laat toe dat bloed in jou penis vloei, sodat jy 'n ereksie op die natuurlike manier kan kry.
ERAFLEX word gebruik om erektiele disfunksie, soms bekend as impotensie, in mans te behandel. Dit is wanneer 'n man nie 'n stywe, regop penis kan kry of hou wat geskik is vir seksuele aktiwiteit nie.
ERAFLEX sal slegs werk as jy seksueel opgewonde is.
ERAFLEX sal nie jou seksdrang verhoog nie.
ERAFLEX is nie vir gebruik in vrouens nie.

2. Wat jy behoort te weet voordat jy ERAFLEX gebruik

Moet nie ERAFLEX 10 neem nie
- Indien jy hipersensitief (allergies) is vir sildenafil of enige van die ander bestanddele van **ERAFLEX** (gelys in afdeling 6).
- Indien jy medisyne naamlik nitrate gebruik, aangesien die kombinasie tot 'n gevaarlike daling in jou bloeddruk kan lei. Vertel jou dokter indien jy enige van hierdie medisyne gebruik wat dikwels gegee word vir verligting van angina pektoris (of "borskaspyn"). Indien jy nie seker is nie, vra jou dokter of apteker.
- Indien jy enige van die medisyne gebruik wat bekend staan as stikstofoksiedskenkers soos amielnitriet ("poppers"), aangesien die kombinasie ook tot 'n gevaarlike daling in jou bloeddruk kan lei.
- Indien jy riokiguat neem. Riokiguat word gebruik vir die behandeling van pulmonêre arteriële hipertensie (d.w.s. hoë bloeddruk in die longe) en chroniese tromboëmboliese pulmonêre hipertensie (d.w.s. hoë bloeddruk in die longe sekondêr tot bloedklonte). Daar is getoon dat FDE5 inhibeerders, soos **ERAFLEX**, die hipotensiewe effekte van hierdie medisyne verhoog. Indien jy riokiguat neem of onseker is, praat met jou dokter.
- Indien jy enige van die medisyne gebruik wat bekend staan as stikstofoksiedskenkers soos amielnitriet ("poppers"), aangesien die kombinasie tot 'n gevaarlike daling in jou bloeddruk kan lei. Vertel jou dokter indien jy enige van hierdie medisyne gebruik wat dikwels gegee word vir verligting van angina pektoris (of "borskaspyn"). Indien jy nie seker is nie, vra jou dokter of apteker.
- Indien jy simetidien (gebruik vir die behandeling van maagsere), ketokonasool of itrakonasool (gebruik om swaminfeksies te behandel), eritromisien of rifampisien (gebruik om infeksies te behandel) of ritonavir of sakwinavir (gebruik om MIV-infeksies te behandel) gebruik.
- Indien jy ernstige probleme met jou hart het (soos onstabiele angina of hartversaking).
- Indien jy al ooit verlies van visie gehad het as gevolg van nie-arteritiese anterior isgemiese optiese neuropatie (NAION).
- Indien jy 'n ernstige nier- of lewerprobleem het.
- Indien jy onlangs 'n beroerte of 'n hartaanval gehad het, of as jy lae bloeddruk het.
- Indien jy sekere seldsame oorgeërfde oogsiektes het (soos *retinitis pigmentosa*).

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met **ERAFLEX:**
- Indien jy probleme met jou hart het. Jou dokter moet noukeurig kyk of jou hart die bykomende spanning van seks kan verduur.
- Indien jy 'n misvorming van jou penis of Peyronie se siekte het.
- Indien jy sekelselanemie ('n abnormaliteit van rooibloedselle), leukemie (kanker van bloedselle), veelvuldige miëloom (kanker van beenmurg) het.
- Indien jy tans 'n maagseer het, of 'n bloedingsprobleem (soos hemofilie).
- Indien jy skielike afname of verlies van visie ervaar, hou op om **ERAFLEX** te neem en kontak onmiddellik jou dokter.

Jy moet nie **ERAFLEX** gebruik saam met behandelings vir pulmonêre arteriële hipertensie (PAH) wat sildenafil of enige ander FDE5 inhibeerders bevat nie.
Jy moet nie **ERAFLEX** saam met enige ander orale of plaaslike behandelings vir erektiele disfunksie gebruik nie.
Jy moet nie **ERAFLEX** neem as jy nie erektiele disfunksie het nie.

Kinders en adolessente
ERAFLEX moet nie aan individue onder die ouderdom van 18 gegee word nie.

Ander medisyne en ERAFLEX
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
- **ERAFLEX** tablette kan inmeng met sommige medisyne, veral dié wat gebruik word om borskaspyn te behandel. In die geval van 'n mediese noodgeval, moet jy jou dokter, apteker of verpleegkundige vertel dat jy **ERAFLEX** geneem het en wanneer jy dit geneem het. Moet nie **ERAFLEX** saam met ander medisyne neem nie, tensy jou dokter vir jou sê dat jy kan.
- Jy moet nie **ERAFLEX** neem as jy medisyne naamlik nitrate gebruik nie, aangesien die kombinasie van hierdie medisyne tot 'n gevaarlike daling in jou bloeddruk kan lei. Vertel altyd jou dokter, apteker of verpleegkundige indien jy enige van hierdie medisyne gebruik wat dikwels gebruik word vir die verligting van angina pektoris (of "borskaspyn").
- Jy moet nie **ERAFLEX** neem indien jy enige van die medisyne gebruik wat bekend staan as stikstofoksiedskenkers soos amielnitriet ("poppers") nie, aangesien die kombinasie ook tot 'n gevaarlike daling in jou bloeddruk kan lei.
- Vertel jou dokter of apteker indien jy reeds riokiguat neem.
- Indien jy medisyne neem wat bekend staan as protease inhibeerders, soos vir die behandeling van MIV, kan jou dokter jou met die laagste dosis (25 mg) **ERAFLEX** begin.
- Sommige pasiënte wat alfa-blokker terapie gebruik vir die behandeling van hoë bloeddruk of prostaatvergroting, kan duiseligheid of ligkoofdigheid ervaar, wat veroorsaak kan word deur lae bloeddruk wanneer hulle vinnig regop sit of opstaan. Sekere pasiënte het hierdie simptome ervaar wanneer hulle **ERAFLEX** met alfa-blokkers geneem het. Dit sal heel waarskynlik binne 4 uur gebeur nadat **ERAFLEX** geneem is. Om die moontlikheid dat hierdie simptome mag voorkom te verminder, moet jy op 'n gereelde daaglikse dosis van jou alfa-blokker wees, voordat jy met **ERAFLEX** begin. Jou dokter kan jou met 'n laer dosis (25 mg) **ERAFLEX** begin.

ERAFLEX 10 met voedsel en vloeistof:
ERAFLEX kan met of sonder kos geneem word. Jy mag egter vind dat **ERAFLEX** langer neem om te begin werk as jy dit saam met 'n swaar maaltyd neem.
Drink van alkohol kan jou vermoë om 'n ereksie te kry tydelik inkort. Om die maksimum voordeel uit jou medisyne te kry, word jy aangeraai om nie oormatige hoeveelhede alkohol te drink voordat jy **ERAFLEX** neem nie.

Swangerskap, borsvoeding en fertiliteit
ERAFLEX is nie aangedui vir gebruik in vrouens nie.

Bestuur en gebruik van masjinerie
ERAFLEX kan duiseligheid veroorsaak en kan visie beïnvloed. Jy moet bewus wees van hoe jy op **ERAFLEX** reageer voordat jy bestuur of masjinerie gebruik.

3. Hoe om ERAFLEX te gebruik

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **ERAFLEX** presies soos jou dokter of apteker vir jou gesê het. Bevestig met jou dokter of apteker as jy nie seker is nie.
Die gewone dosis is 50 mg, geneem ongeveer een uur voor seksuele aktiwiteit. Hierdie dosis kan deur jou dokter verhoog word tot 100 mg of verlaag word tot 25 mg. Sluk die tablet heel met bietjie water.
ERAFLEX sal jou net help om 'n ereksie te kry as jy seksueel gestimuleer word. Die tyd wat **ERAFLEX** neem om te werk, verskil van persoon tot persoon, maar dit neem gewoonlik tussen 'n halfuur en een uur.
Indien **ERAFLEX** jou nie help om 'n ereksie te kry nie of as jou ereksie nie lank genoeg duur vir jou om seksuele omgang te voltooi nie, moet jy jou dokter vertel. Jy moet nie **ERAFLEX** meer as een keer per dag gebruik nie.
Indien jy die indruk het dat die effek van **ERAFLEX** te sterk of te swak is, vertel jou dokter of apteker.

Indien jy meer ERAFLEX neem as wat jy behoort te neem
Die neem van 'n dosis hoër as 100 mg verhoog nie die effek van **ERAFLEX** nie. Dit sal egter lei tot 'n toename in ongewenste effekte en hul erns. In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

4. Moontlike newe-effekte

ERAFLEX kan newe-effekte hê.
Nie al die newe-effekte wat vir **ERAFLEX** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verslag of indien jy enige ongewenste effekte ervaar terwyl jy **ERAFLEX** neem, kontak asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om **ERAFLEX** te neem en sê onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel wat probleme kan veroorsaak om te sluk of asem te haal.
- uitslag of jeuk,
- floute.

Al hierdie newe-effekte is baie ernstig. Indien jy dit ervaar, het jy moontlik 'n ernstige reaksie op **ERAFLEX** gehad. Jy mag dringende mediese aandag of hospitalisasie benodig.

Vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:
Minder algemeen
- borskaspyn,
- langdurige en soms pynlike ereksies,
- 'n skielike afname of verlies van visie,
- ernstige velreaksies (simptome kan erge afskilfering en swelling van die vel, blase in die mond, geslagsdele en om die oë, koors insluit),
- aanvalle of stuipe.

Dit is alles ernstige newe-effekte. Jy benodig dalk dringende mediese aandag.

Sê vir jou dokter indien jy enige van die volgende waarneem:
Gereeld
- hoofpyn, duiseligheid
- naarheid, slegte spysvertering,
- gesigsgloede, warm gloed,
- kleurtint tot visie, dowwe visie, visuele versteuring,
- toe neus.

Minder gereeld
- braking
- veluitslag,
- oogirritasie, bloedbelope oë/rooi oë, oogpyn, sien van ligflitse, visuele helderheid, ligsensitiwiteit, waterige oë,
- bonsende hartklop, vinnige hartklop, hoë bloeddruk, lae bloeddruk,
- spierpyn,
- slaperig voel, verminderde gevoel van aanraking,
- vertigo, suis in die ore,
- droë mond,
- verstopte of geblokte sinusse, ontsteking van die voering van die neus, neusbloeding,
- boonste abdominale pyn, gastroësofageale refluks siekte (simptome sluit soolbrand in),
- teenwoordigheid van bloed in uriene,
- pyn in die arms of bene,
- voel warm, voel moeg,
- floute, beroerte, hartaanval, onreëlmatige hartklop, tydelike verminderde bloedvloei na dele van die brein,
- gevoel van toetrek van die keel, gevoellose mond,
- bloeding aan die agterkant van die oog, dubbelvisie, verminderde skerpte van visie, abnormale sensasie in die oog, swelling van die oog of ooglid, klein deeltjies of kolletjies in jou visie, sien ligkringe rondom ligte, verwyding van die pupil van die oog , verkleuring van die wit van die oog,
- peniesbloeding, teenwoordigheid van bloed in semen,
- droë neus, swelling van die binnekant van die neus,
- voel prikkelbaar,
- skielike afname of verlies van gehoor.

Frekwensie onbekend
- onstabiele angina ('n harttoestand).
- skielike dood.
- retinale loslating (wat kan lyk soos klein spikkels in jou gesigsveld).

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief jou dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **ERAFLEX.**

5. Hoe om ERAFLEX te bewaar

Bewaar by of benede 25 °C.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Hou die HDPE houers dig toe.
Berg in die oorspronklike verpakking om sodoende teen lig en vog te beskerm.
HOU BUITE DIE BEREIK VAN KINDERS.
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat aangebring is op die stulpstrook/etiket/karton/bottel nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat ERAFLEX bevat
ERAFLEX 25 mg:
Die aktiewe bestanddeel in **ERAFLEX** is Sildenafilsitraat gelykstaande aan 25 mg Sildenafil.
ERAFLEX 50 mg:
Die aktiewe bestanddeel in **ERAFLEX** is Sildenafilsitraat gelykstaande aan 50 mg Sildenafil.
ERAFLEX 100 mg:
Die aktiewe bestanddeel in **ERAFLEX** is Sildenafilsitraat gelykstaande aan 100 mg Sildenafil.

Ander bestanddele is: Natriumkruiskarmellose, dibasiese kalsiumfosfaatdihidraat, hipromellose, magnesiumstearaat, mikrokristallyne sellulose. Filmbedekking insluitend hipromellose, titaandioksied, triasetien en FD & C blou # 2/Indigo Karmyn aluminiummeer.

Hoe ERAFLEX lyk en inhoud van die pak
ERAFLEX 25 mg
Blou gekleurde, diamantvormige, filmbedekte tablette met "CL 35" aan die een kant gegraveer en glad aan die ander kant.
ERAFLEX 50 mg
Blou gekleurde, diamantvormige, filmbedekte tablette met "CL 36" aan die een kant gegraveer en glad aan die ander kant.
ERAFLEX 100 mg
Blou gekleurde, diamantvormige, filmbedekte tablette met "CL 37" aan die een kant gegraveer en glad aan die ander kant.

Inhoud van die pak:
Stulpverpakking:
Aluminiumfoelie van 6-8 gsm hitteseëllak as die dekmateriaal en deursigtige PVC-film bedek met PVdC as die vormingsmateriaal.
Verpakkingsgrootte sluit in 1's, 2's, 4's, 8's, 10's en 12's tablette
Houer verpakking:
40 ml ronde wit HDPE houer met 33 - 400 nekafwerking toegemaak met kinderbestande sluiting met pulp en hitteseëlvoering.
Verpakkingsgrootte 30 tablette
*Nie alle verpakkingsgroottes sal bemark word nie.

Houer van die Registrasiesertifikaat
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid Afrika

Hierdie inligtingstuk was laas hersien in
31 Mei 2024

Registrasienommer
ERAFLEX 25 mg: 46/7.1.5/0254
ERAFLEX 50 mg: 46/7.1.5/0255
ERAFLEX 100 mg: 46/7.1.5/0256

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169.

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MACLEODS

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PACKAGING RESEARCH & DEVELOPMENT

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Update in section 4.0 Possible side effects, Retinal detachment (which may appear as tiny specks through your field of vision) is added in frequency unknown, Exclude Professional Information & Dimensions change.

1. Product: ERAFLEX 25/50/100 MG (Sildenafil Film Coated Tablets 25/50/100 mg)	
2. Country: South Africa (Private Market)	**3. Packaging component: Patient Information**
4. No. of Colours: 1 Colour	**5. Pantone Shade No.: Black**
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	**8. Dimensions: 335 (L) x 320 (W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM03984802**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 33919 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: PM03984801**
15. Revision no: 01	**16. AW File name: Z:\Sildenafil Tablets\SA Private Market\02\Sildenafil 25-50-100 mg Tablets PIL - PM03984802.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
Vanita Rajool 25/01/24		25/01/24	27/01/24	29/01/24	29/01/24

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa Private Market	PM03984801	22/12/22	16/02/2023
2) Update in section 4.0 Possible side effects, Retinal detachment (which may appear as tiny specks through your field of vision) is added in frequency unknown, Exclude Professional Information & Dimensions change.	PM03984802		

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