Front Side

SCHEDULING STATUS: S4

1. NAME OF THE MEDICINE

PRAVLEX SR 0,4 MG (Sustained release capsule)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each **PRAVLEX SR 0,4 MG** sustained release capsule contains 0,4 mg tamsulosin hydrochloride.
Sugar free
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.
For a full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Sustained release capsule
PRAVLEX SR 0,4 MG
Olive green opaque/ orange opaque, size 2, hard gelatin capsules containing free flowing white to off white spheroids with "CL 23" on cap and "0.4" on the body imprinted with black ink.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
PRAVLEX SR 0,4 MG is indicated for the treatment of functional symptoms of benign prostatic hyperplasia (BPH) in adult males.
Efficacy in children with neurogenic bladder has not been demonstrated.

4.2 Posology and method of administration
Posology:
Adults:
One capsule daily.
Special populations
No dose adjustment is warranted in renal impairment.
No dose adjustment is warranted in patients with mild to moderate hepatic insufficiency (see section 4.3).
Paediatric population
There is no indication for use of **PRAVLEX SR 0,4 MG** in children.
The safety and efficacy of tamsulosin in children <18 years have not been established.

Method of administration
PRAVLEX SR 0,4 MG is administered orally after breakfast or the first meal of the day.
The capsule should be swallowed whole and must not be crunched or chewed, as this will interfere with the sustained release property of the active ingredient.

4.3 Contraindications
PRAVLEX SR 0,4 MG is contraindicated in patients with:
- Hypersensitivity to tamsulosin hydrochloride, or any other components of **PRAVLEX SR 0,4 MG** (see section 6.1).
- A history of orthostatic hypotension.
- Hepatic insufficiency.
- **PRAVLEX SR 0,4 MG** should not be used in combination with strong inhibitors of CYP3A4, e.g. ketoconazole.

4.4 Special warnings and precautions for use
A decrease in blood pressure can take place during therapy with **PRAVLEX SR 0,4 MG**, as a result of which orthostatic hypotension and syncope can occur. At the first signs of orthostatic hypotension (dizziness, weakness), the patient should sit or lie down until the symptoms have disappeared.
Before therapy with **PRAVLEX SR 0,4 MG** is initiated, the patient should be examined in order to exclude the presence of other conditions which can cause the same symptoms as benign prostatic hyperplasia. Digital rectal examination, and when necessary, determination of prostate specific antigen (PSA) should be performed before treatment and at regular intervals afterwards.
The treatment of patients with severe renal impairment (creatinine clearance of < 10 ml/min) should be approached with caution, as these patients have not been studied.
The "Intraoperative Floppy Iris Syndrome" (IFIS, a variant of small pupil syndrome) has been observed during cataract and glaucoma surgery in some patients previously treated with tamsulosin. IFIS may increase the risk of eye complications during and after the operation. Discontinuing tamsulosin 1 to 2 weeks prior to cataract or glaucoma surgery is anecdotally considered helpful, but the benefit of treatment discontinuation has not yet been established. IFIS has also been reported in patients who had discontinued tamsulosin for a longer period prior to eye surgery.
The initiation of therapy with **PRAVLEX SR 0,4 MG** in patients for whom cataract or glaucoma surgery is scheduled is not recommended. During pre-operative assessment, surgeons and ophthalmic teams should consider whether patients scheduled for cataract or glaucoma surgery are being or have been treated with **PRAVLEX SR 0,4 MG** in order to ensure that appropriate measures will be in place to manage the IFIS during surgery.
PRAVLEX SR 0,4 MG should not be given in combination with strong inhibitors of CYP3A4 in patients with poor metaboliser CYP2D6 phenotype.
PRAVLEX SR 0,4 MG should be used with caution in combination with strong and moderate inhibitors of CYP3A4 (see section 4.5).
PRAVLEX SR 0,4 MG is intended for adult male patients only.

4.5 Interaction with other medicines and other forms of interaction
No interactions have been seen when tamsulosin was given concomitantly with either atenolol, enalapril, or theophylline.

Concomitant cimetidine brings about a rise in plasma levels of tamsulosin and concomitant furosemide brings about a fall, but as levels remain within the normal range dosages need not be changed.

Diazepam, propanolol, trichlormethazide, chlormadinone, amitriptyline, diclofenac, glibenclamide, simvastatin and warfarin do not change the free fraction of tamsulosin in human plasma, *in vitro*. Neither does tamsulosin change the free fractions of diazepam, propanolol, trichlormethiazide and chlormadinone.

Diclofenac and warfarin, may increase the elimination rate of tamsulosin.

Concomitant administration of **PRAVLEX SR 0,4 MG** with strong inhibitors of CYP3A4 may lead to increased exposure to tamsulosin hydrochloride. Concomitant administration with ketoconazole (a known strong CYP3A4 inhibitor) resulted in an increase in AUC and C_{max} of tamsulosin hydrochloride by a factor of 2,8 and 2,2, respectively. Since CYP2D6 poor metabolisers cannot be readily identified and the potential for significant increase in tamsulosin hydrochloride exposure exists when **PRAVLEX SR 0,4 MG** is co-administered with strong CYP3A4 inhibitors in CYP2D6 poor metabolisers, **PRAVLEX SR 0,4 MG** should not be given in combination with strong inhibitors of CYP3A4 (see section 4.3). **PRAVLEX SR 0,4 MG** should be given with caution in combination with moderate inhibitors of CYP3A4.
Concomitant administration of tamsulosin with paroxetine, a strong inhibitor of CYP2D6, resulted in a C_{max} and AUC of tamsulosin that increased by a factor of 1,3 and 1,6, respectively, but these increases are not considered clinically relevant.

Concurrent administration of other alpha1-adrenoceptor antagonists could lead to hypotensive effects.

4.6 Fertility, pregnancy and lactation
Pregnancy
PRAVLEX SR 0,4 MG is not indicated for use in women.
Fertility
Ejaculation disorders have been observed in short and long term clinical studies with tamsulosin. Events of ejaculation disorder, retrograde ejaculation and ejaculation failure have been reported post-marketing.

4.7 Effects on ability to drive and use machines
No data is available on whether **PRAVLEX SR 0,4 MG** adversely affects the ability to drive or operate machinery. However, in this respect, patients should be aware of the fact that dizziness, drowsiness, blurred vision and syncope may occur.

4.8 Undesirable effects
Tabulated summary of adverse events

System organ class	Frequency	Undesirable effect
Nervous system disorders	Frequent	Dizziness
	Less frequent	Headache, syncope
Eye disorders	Frequency unknown	Vision blurred, visual impairment
Cardiac disorders	Less frequent	Palpitations
Vascular disorders	Less frequent	Orthostatic hypotension
Respiratory, thoracic and mediastinal	Less frequent	Rhinitis
	Frequency unknown	Epistaxis
Gastrointestinal disorders	Less frequent	Constipation, diarrhoea, nausea, vomiting
	Frequency unknown	Dry mouth
Skin and subcutaneous tissue disorders	Less frequent	Rash, pruritis, urticaria, angioedema, Stevens-Johnson syndrome
	Frequency unknown	Erythema multiforma, dermatitis exfoliative
Reproductive systems and breast disorders	Frequent	Ejaculation disorders, including retrograde ejaculation and ejaculation failure
	Less frequent	Priapism
General disorders and administration site conditions	Less frequent	Asthenia

Drowsiness or oedema can occur.

During cataract and glaucoma surgery a small pupil situation, known as Intraoperative Floppy Iris Syndrome (IFIS), has been associated with therapy of tamsulosin during post-marketing surveillance (see also Section 4.4).
In addition to the adverse events listed above, atrial fibrillation, dysrhythmia, tachycardia and dyspnoea have been reported in association with tamsulosin use. Because these spontaneously reported events are from the worldwide post-marketing experience, the frequency of events and the role of tamsulosin in their causation cannot be estimated from the available data.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose
Overdosage with **PRAVLEX SR 0,4 MG** may result in severe hypotensive effects. Severe hypotensive effects have been observed at different levels of overdosing.
Treatment:
In case of acute hypotension occurring after overdosage, cardiovascular support should be given. Blood pressure can be restored and heart rate brought back to normal, by lying the patient down. If this does not help then volume expanders, and when necessary, vasopressors could be employed.
Renal function should be monitored and general supportive measures applied. Dialysis is unlikely to be of help as tamsulosin is very highly bound to plasma proteins.
Measures such as emesis can be taken to impede absorption. When large quantities are involved, activated charcoal and an osmotic laxative, such as sodium sulphate, can be administered.

5. PHARMACOLOGICAL PROPERTIES

Category and Class: A.34 Other
Pharmacotherapeutic group: Alpha1-adrenoceptor antagonist.
ATC code: G04CA02

5.1 Pharmacodynamic properties
Mechanism of action:
Tamsulosin binds selectively and competitively to postsynaptic alpha1-receptors, in particular to the subtype $alpha_{1A}$, and $alpha_{1D}$ which bring about relaxation of the smooth muscle of the prostate, whereby tension is reduced.

5.2 Pharmacokinetic properties
Absorption
Tamsulosin hydrochloride is absorbed from the intestine and is almost completely bioavailable.
Absorption of tamsulosin hydrochloride is reduced by a recent meal.
Uniformity of absorption can be improved by the patient always taking **PRAVLEX SR 0,4 MG** after the same meal each day.
Tamsulosin shows linear kinetics.
After a single dose of tamsulosin in the fed state, plasma levels of tamsulosin peak at around 6 hours and, in the steady state, which is reached by day 5 of multiple dosing, C_{max} in patients is about two thirds higher than that reached after a single dose. Although this was seen in elderly patients, the same finding would also be expected in young ones.
There is a considerable inter-patient variation in plasma levels both after single and multiple dosing.
Distribution
In man, tamsulosin is about 99 % bound to plasma proteins and volume of distribution is small (about 0,2 l/kg).
Biotransformation
Tamsulosin has a low first pass effect, being metabolised slowly. Most tamsulosin is present in plasma in the form of unchanged medicine. It is metabolised in the liver.
In rats, hardly any induction of microsomal liver enzymes was seen to be caused by tamsulosin.
In vitro results suggest that CYP3A4 and also CYP2D6 are involved in metabolism, with possible minor contributions to tamsulosin hydrochloride metabolism by other CYP isozymes. Inhibition of CYP3A4 and CYP2D6 drug metabolising enzymes may lead to increased exposure to tamsulosin hydrochloride (see Sections 4.4 and 4.5).
No dose adjustment is warranted in hepatic insufficiency.
None of the metabolites are more active than the original compound.
Elimination
Tamsulosin and its metabolites are mainly excreted in the urine with about 9 % of a dose being present in the form of unchanged medicine.
After a single dose of tamsulosin in the fed state, and in the steady state in patients, elimination half-lives of about 10 and 13 hours respectively have been measured.
The presence of renal impairment does not warrant lowering the dose.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Calcium stearate, methacrylic acid copolymer, microcrystalline cellulose, Polysorbate 80, sodium lauryl sulfate, triacetin.
Capsule shell: gelatin, FD & C Blue 2 (C.I. 73015), Iron oxide black (C.I. 77499), Iron oxide red (C.I. 77491), Iron oxide yellow (C.I.77492) and titanium dioxide (C.I. 77891), sodium lauryl sulfate.
Capsule body: gelatin, Iron oxide red (C.I. 77491), Iron oxide yellow (C.I.77492) and titanium dioxide (C.I. 77891) and sodium lauryl sulfate.
Hard gelatin capsule contains black edible printing ink.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months for HDPE container pack from the date of manufacture.
36 months for blister pack from the date of manufacture.

6.4 Special precautions for storage
Store at or below 25 °C (room temperature). Protect from light and moisture.
Keep the blisters in the carton until required for use
Store in the original package in order to protect from light and moisture.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container
Blister pack:
Capsules are packed in Clear Film PVC/PE/PVdC, 250 µ /25 µ/90 GSM as forming material and Plain silver coloured aluminum foil, 25 µ, 6-8 GSM as the lidding material.
Pack size: 30's
HDPE Container Pack:
Capsules are packed in 30 cc, round white HDPE bottle with 28-400 neck finish closed with a white 28 mm child resistant closure with pulp and heat seal liner.
Pack size: 30's
Not all packs and pack size are necessarily marketed.

6.6 Special precautions for disposal and other handling
No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. 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.

8. REGISTRATION NUMBER(S)

PRAVLEX SR 0,4 MG : 48/34/0855

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

04 August 2022

10. DATE OF REVISION OF THE TEXT

–

PRAVLEX SR 0,4 MG
(Sustained Release Capsules)
PM03986001

400 mm

335 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PRAVLEX SR 0,4 MG (Sustained release capsule)
Tamsulosin hydrochloride
Sugar free

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

Read all of this leaflet carefully before you start taking PRAVLEX SR 0,4 MG
- 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.
- **PRAVLEX SR 0,4 MG** 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 **PRAVLEX SR 0,4 MG** is and what it is used for
2. What you need to know before you take **PRAVLEX SR 0,4 MG**
3. How to take **PRAVLEX SR 0,4 MG**
4. Possible side effects
5. How to store **PRAVLEX SR 0,4 MG**
6. Contents of the pack and other information

1. What **PRAVLEX SR 0,4 MG** is and what it is used for

PRAVLEX SR 0,4 MG is a modified release capsule which contains a medicine called tamsulosin. It belongs to a group of medicines called 'alpha blockers' (or alpha1A-adrenoceptor antagonists).

PRAVLEX SR 0,4 MG is used to treat the lower urinary tract symptoms (LUTS) of a common condition called benign prostatic hyperplasia (BPH). This is when the prostate gland gets bigger. The prostate gland is found just below a man's bladder. When your prostate gland gets bigger, it can:
- Make it difficult for you to start urinating (peeing)
- Mean you take longer or have to urinate more often
- Lead to the feeling that you still need to urinate again, even though you have just done so
- Cause you to get up several times in the night to urinate

PRAVLEX SR 0,4 MG relieves these problems by:
- Relaxing the muscles in the prostate gland
- Relaxing the muscles in the urethra (the tube from the bladder to the outside of the body). This lets urine pass more freely through the urethra, making it easier to urinate.

2. What you need to know before you take PRAVLEX SR 0,4 MG

PRAVLEX SR 0,4 MG should be used only by men.
Do not take PRAVLEX SR 0,4 MG if:
- You are allergic (hypersensitive) to tamsulosin or any of the other ingredients of this medicine (listed in Section 6 below)
- You are taking certain medicines called ketoconazole to treat fungal infections.
- You faint or get dizzy or weak when you sit or stand up suddenly.
- You suffer from liver disease.

Warnings and precautions
Take special care with **PRAVLEX SR 0,4 MG**
A drop in blood pressure has been reported during the use of tamsulosin. On first feeling of dizziness, it is necessary to sit down or lay down until disappearance of these signs.
Tell your doctor if you have any problems with your kidneys.

If you are planning to undergo cataract surgery, please inform your doctor that you are taking or have recently taken tamsulosin capsules.

Use in children and adolescents
Do not give this medicine to children or adolescents under 18 years because safety and efficacy have not been established in this population.

Other medicines and PRAVLEX SR 0,4 MG
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Tamsulosin can interact with:
- diclofenac (a pain killer and anti-inflammatory medicine) and warfarin, used to thin the blood. They can speed up the removal of tamsuosin from your body, thereby shortening the time tamsulosin is effective.
- Medicines that may decreae the removal of tamsulosin from the body (for example ketoconazole, erythromycin).
- another alpha1-adrenoceptor blockers (such as doxasin and terazosin), the combination may lower your blood pressure, causing dizziness or light-headedness

PRAVLEX SR 0,4 MG with food and drink:
PRAVLEX SR 0,4 MG must be taken with breakfast or the first meal of the day.

Pregnancy, breastfeeding and fertility
PRAVLEX SR 0,4 MG is only for use in men.

Fertility
Difficulties with ejaculation have ben reported in association with tamsulosin use (see Section 4 Possible side effects).

Driving and using machines
PRAVLEX SR 0,4 MG may cause dizziness, drowsiness, blurred vision or fainting. Do not drive or operate machinery if you experience these side effects.

3. How to take PRAVLEX SR 0,4 MG

Do not share medicines prescribed for you with any other person.
Always take **PRAVLEX SR 0,4 MG** exactly as your doctor has instructed you.
You should check with your doctor or pharmacist if you are not sure.
The recommended dose of **PRAVLEX SR 0,4 MG** is one capsule daily.
PRAVLEX SR 0,4 MG must be taken orally after breakfast or the first meal of the day.
The capsule should be swallowed whole and must not be crunched or chewed.
If you have the impression that the effect of **PRAVLEX SR 0,4 MG** is too strong or too weak, talk to your doctor or pharmacist.
If you take more PRAVLEX SR 0,4 MG than you should
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Back Side

400 mm

If you forget to take PRAVLEX SR 0,4 MG
It is important to take your **PRAVLEX SR 0,4 MG** capsules regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take two doses at the same time, to make up for a missed dose.

If you stop taking PRAVLEX SR 0,4 MG
Do not stop taking **PRAVLEX SR 0,4 MG** without getting your doctor's advice first. Always take **PRAVLEX SR 0,4 MG** for as long as your doctor has prescribed.

4. Possible side effects

PRAVLEX SR 0,4 MG can have side effects.
Not all the side effects reported for **PRAVLEX SR 0,4 MG** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **PRAVLEX SR 0,4 MG**, please consult your healthcare provider for advice.

If any of the following happens stop taking **PRAVLEX SR 0,4 MG** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling around the hands, feet, eyes, lips or tongue
- difficulty swallowing or breathing
- rash or itchy skin, inflammation or blistering.

These are all very serious side effects. If you have them, you may have had a serious reaction to **PRAVLEX SR 0,4 MG**. 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:
- Itching, hives,
- Stevens-Johnson syndrome – hypersensitivity reaction with purplish spots or patches on the skin, peeling of the skin, (high) fever, joint pain and/or eye inflammation.

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:
- Dizziness (can occur especially on abrupt alteration of the position – when sitting up or standing up from the lying position).
- Difficulties with ejaculation, little or no semen ejaculated at sexual climax, cloudy urine following sexual climax.

Less frequent side effects
- Headaches, fainting,
- Fast beating or pounding heart rate,
- Low blood pressure that happens when standing up from sitting or lying down,
- Runny or stuffy nose,
- Constipation, diarrhoea, feeling sick (nausea), vomiting,
- Painful long-lasting unwanted erection which requires immediate medical assistance,
- Feeling of weakness.

Side effects with unknown frequency:
- Disturbances of vision, blurred vision
- Bleeding from the nose
- Dry mouth
- Rash with red irregular spots, scaling of the skin

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
Not all the side effects reported for **PRAVLEX SR 0,4 MG** are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking **PRAVLEX SR 0,4 MG**, please consult your healthcare provider for advice.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 **PRAVLEX SR 0,4 MG.**

5. How to store PRAVLEX SR 0,4 MG

Store at or below 25 °C (room temperature). Protect from light and moisture.
KEEP OUT OF THE REACH OF CHILDREN.
Keep the blisters in the carton until required for use.
Store in the original package / container.
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 pack and other information

What PRAVLEX SR 0,4 MG Capsules contains
The active ingredient is tamsulosin hydrochloride.

The other ingredients are:
Calcium stearate, methacrylic acid copolymer, microcrystalline cellulose, Polysorbate 80, sodium lauryl sulphate, triacetin.
Capsule shell: gelatin, FD & C Blue 2 (C.I. 73015), Iron oxide black (C.I. 77499), Iron oxide red (C.I. 77491), Iron oxide yellow (C.I.77492) and titanium dioxide (C.I. 77891) and sodium lauryl sulfate.
Capsule body: gelatin, Iron oxide red (C.I. 77491), Iron oxide yellow (C.I.77492) and titanium dioxide (C.I. 77891) and sodium lauryl sulfate.
Hard gelatin capsule contains black edible printing ink.

What PRAVLEX looks like and contents of the pack
PRAVLEX SR 0,4 MG Capsules:
Olive green opaque/ orange opaque, size 2, hard gelatin capsules containing free flowing white to off white spheroids with "CL 23" on cap and "0.4" on the body imprinted with black ink.

Blister pack:
Capsules are packed in Clear Film PVC/PE/PVdC, 250 µ /25 µ/90 GSM as forming material and Plain silver coloured aluminum foil, 25 µ, 6-8 GSM as the lidding material.
Pack size: 30's

HDPE Container Pack:
Capsules are packed in 30 cc, round white HDPE bottle with 28-400 neck finish closed with a white 28 mm child resistant closure with pulp and heat seal liner.
Pack size: 30's
Not all packs and pack size are necessarily marketed.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

This leaflet was last revised in
04 August 2022

Registration number
PRAVLEX SR 0,4 MG: 48/34/0855

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**.

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

PRAVLEX SR 0,4 MG
(Vrystellingsgereguleerde Kapsule)
Tamsulosienhidrochloried
Suikervry

Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per dosis eenheid, dit wil sê essensieel 'natriumvry'.

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy PRAVLEX SR 0,4 MG begin neem
- 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
- **PRAVLEX SR 0,4 MG** 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 **PRAVLEX SR 0,4 MG** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **PRAVLEX SR 0,4 MG** neem
3. Hoe om **PRAVLEX SR 0,4 MG** te neem
4. Moontlike newe-effekte
5. Hoe om **PRAVLEX SR 0,4 MG** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat PRAVLEX SR 0,4 MG is en waarvoor dit gebruik word

PRAVLEX SR 0,4 MG is 'n gewysigde vrystellings kapsule wat 'n medisyne genaamd tamsulosien bevat. Dit behoort aan 'n groep medisyne wat 'alfablokkers' (of alfa1A-adrenoreseptorantagoniste) genoem word.
PRAVLEX SR 0,4 MG word gebruik om die laer urienwegsimptome (LUWS) van 'n algemene toestand genaamd benigne prostaat hiperplasie (BPH) te behandel. Dit is wanneer die prostaatklier groter word. Die prostaatklier word net onder 'n man se blaas gevind. Wanneer jou prostaatklier groter word, kan dit:
- Vir jou moeilik maak om te begin urineer (piepie)
- Beteken dat jy langer neem of meer gereeld moet urineer
- Lei tot die gevoel dat jy steeds weer moet urineer, al het jy dit pas gedoen
- Veroorsaak dat jy verskeie kere in die nag opstaan om te urineer

PRAVLEX SR 0,4 MG verlig hierdie probleme deur:
- Die spiere in die prostaatklier te ontspan
- Die spiere in die uretra te ontspan (die buis vanaf die blaas na die buitekant van die liggaam). Dit laat uriene meer vrylik deur die uretra beweeg, wat dit makliker maak om te urineer.

2. Wat jy behoort te weet voordat jy PRAVLEX SR 0,4 MG neem

PRAVLEX SR 0,4 MG moet slegs deur mans gebruik word.

Moet nie PRAVLEX SR 0,4 MG neem nie indien:
- Jy allergies (hipersensitief) is vir tamsulosien of enige van die ander bestanddele van hierdie medisyne (gelys in afdeling 6 hieronder).
- Jy sekere medisyne neem, naamlik ketokonasool om swaminfeksies te behandel.
- Jy flou word, of duiselig of swak word, wanneer jy skielik sit of opstaan.
- Jy aan lewersiekte ly.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met **PRAVLEX SR 0,4 MG**
'n Verlaging in bloeddruk is aangemeld tydens die gebruik van tamsulosien. By die eerste gevoel van duiseligheid is dit nodig om te gaan sit of lê, totdat hierdie tekens verdwyn.
Vertel jou dokter indien jy enige probleme met jou niere het.

Indien jy van plan is om katarakchirurgie te ondergaan, stel asseblief jou dokter in kennis dat jy tamsulosienkapsules neem of onlangs geneem het.

Gebruik in kinders en adolessente
Moet nie hierdie medisyne aan kinders of adolessente onder 18 jaar gee nie, aangesien veiligheid en doeltreffendheid nie in hierdie populasie vasgestel is nie.

Ander medisyne en PRAVLEX SR 0,4 MG
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Tamsulosien kan interaksie hê met:
- diklofenak ('n pynstiller en anti-inflammatoriese middel) en warfarien, wat gebruik word om die bloed te verdun. Hulle kan die verwydering van tamsulosien uit jou liggaam bespoedig en sodoende die tyd wat tamsulosien effektief is, verkort.
- Medisyne wat die verwydering van tamsulosien uit die liggaam kan verminder (byvoorbeeld ketokonasool, eritromisien).
- ander alfa1-adrenoreseptorblokkers (soos doksasien en terasosien), die kombinasie kan jou bloeddruk verlaag, duiseligheid of lighoofdigheid veroorsaak.

PRAVLEX SR 0,4 MG met voedsel en vloeistof:
PRAVLEX SR 0,4 MG moet saam met ontbyt of die eerste maaltyd van die dag geneem word.

Swangerskap, borsvoeding en fertiliteit
PRAVLEX SR 0,4 MG is slegs vir gebruik in mans.

Fertiliteit
Probleme met ejakulasie is aangemeld in assosiasie met tamsulosiengebruik (sien Afdeling 4 Moontlike newe-effekte).

Bestuur en gebruik van masjinerie
PRAVLEX SR 0,4 MG kan duiseligheid, lomerigheid, dowwe visie of floute veroorsaak. Moet nie bestuur of masjienerie gebruik indien jy hierdie newe-effekte ervaar nie.

3. Hoe om PRAVLEX SR 0,4 MG te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **PRAVLEX SR 0,4 MG** presies soos jou dokter vir jou voorgeskryf het.
Vra vir jou dokter of apteker indien jy nie seker is nie.
Die aanbevole dosis van **PRAVLEX SR 0,4 MG** is een kapsule per dag.
PRAVLEX SR 0,4 MG moet mondelings na ontbyt, of die eerste maaltyd van die dag, geneem word.
Die kapsule moet heel ingesluk word en moet nie fyngemaak of gekou word nie.
Indien jy die indruk het dat die effek van **PRAVLEX SR 0,4 MG** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer PRAVLEX SR 0,4 MG neem as wat jy behoort te neem
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om PRAVLEX SR 0,4 MG te neem
Dit is belangrik om jou **PRAVLEX SR 0,4 MG** kapsules gereeld, op dieselfde tyd, elke dag te neem. Indien jy vergeet om 'n dosis te neem, neem dit so gou as wat jy daarvan onthou, tensy dit tyd is vir jou volgende dosis. Moet nie twee dosisse gelyktydig neem, om op te maak vir 'n vergete dosis nie.

Indien jy ophou om PRAVLEX SR 0,4 MG te neem
Moet nie ophou om **PRAVLEX SR 0,4 MG** te neem sonder om eers jou dokter se advies te kry nie. Neem altyd **PRAVLEX SR 0,4 MG** vir so lank as wat jou dokter dit voorgeskryf het.

4. Moontlike newe-effekte

PRAVLEX SR 0,4 MG kan newe-effekte hê.
Nie al die newe-effekte wat vir **PRAVLEX SR 0,4 MG** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of jy enige ongunstige effekte ondervind terwyl jy **PRAVLEX SR 0,4 MG** neem, kontak asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om **PRAVLEX SR 0,4 MG** te neem en vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- swelling rondom die hande, voete, oë, lippe of tong
- probleme om te sluk of asem te haal
- uitslag of jeukerige vel, ontsteking of blase.

Hierdie is alles baie ernstige newe-effekte. As jy dit het, het jy moontlik 'n ernstige reaksie op **PRAVLEX SR 0,4 MG** gehad. Jy het moontlik dringende mediese aandag of hospitalisasie nodig.
Vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:
- Jeuk, galbulte,

- Stevens-Johnson sindroom – hipersensitiwiteitsreaksie met perserige spikkels of kolle op die vel, afskilfering van die vel, (hoë) koors, gewrigspyn en/of oogontsteking.

Hierdie is alles ernstige newe-effekte. Jy benodig moontlik dringende mediese aandag.

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereelde newe-effekte:
- Duiseligheid (kan veral tydens skielike verandering in die posisie voorkom – wanneer regop sit of opstaan vanuit die lêende posisie).
- Probleme met ejakulasie, min of geen semen ejakuleer tydens seksuele klimaks, troebel uriene ná seksuele klimaks.

Minder gereelde newe-effekte:
- Hoofpyne, floute,
- Vinnige klop of bonsende hartklop,
- Lae bloeddruk wat plaasvind wanneer opstaan uit sit- of lê posisie,
- Loop- of toe neus,
- Hardlywigheid, diaree, siek voel (naarheid), braking,
- Pynlike langdurige ongewenste ereksie wat onmiddellike mediese hulp vereis,
- Gevoel van swakheid.

Newe-effekte met onbekende frekwensie:
- Versteurings van visie, dowwe visie
- Bloeding uit die neus
- Droë mond
- Uitslag met rooi onreëlmatige kolle, afskilfering van die vel

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief jou dokter of apteker in kennis.
Nie al die newe-effekte wat vir **PRAVLEX SR 0,4 MG** aangemeld is, is in hierdie inligtingstuk ingesluit nie.
Sou jou algemene gesondheid versleg of indien jy enige ongunstige effekte ervaar terwyl jy **PRAVLEX SR 0,4 MG** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys word nie. 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 **PRAVLEX SR 0,4 MG**.

5. Hoe om PRAVLEX SR 0,4 MG te bewaar

Bewaar by of benede 25°C (kamertemperatuur). Beskerm teen lig en vog.
HOU BUITE DIE BEREIK VAN KINDERS
Hou die stolpverpakking in die karton tot benodig vir gebruik.
Stoor in die oorspronklike verpakking/houer.
Moet nie in 'n badkamer bêre nie
Moet nie na die vervaldatum wat aangebring is op die stulpstrook/etiket/karton/bottel gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat PRAVLEX SR 0,4 MG Kapules bevat
Die aktiewe bestanddeel is tamsulosienhidrochloried.

Die ander bestanddele is:
Kalsiumstearaat, metakrielsuurkopolimeer, mikrokristallyne sellulose, Polisorbaat 80, natriumlaurielsulfaat, triasetien.
Kapsule doppie: gelatien, FD & C Blou 2 (C.I. 73015), swart ysteroksied (C.I. 77499), rooi ysteroksied (C.I. 77491), geel ysteroksied (C.I. 77492) en titaandioksied (C.I. 77891) en natriumlaurielsulfaat.
Kapsule liggaam: gelatien, rooi ysteroksied (C.I. 77491), geel ysteroksied (C.I.77492) en titaandioksied (C.I. 77891) en natriumlaurielsulfaat.
Harde gelatienkapsule bevat swart eetbare druk ink.

Hoe PRAVLEX SR 0,4 MG lyk en inhoud van die pak
PRAVLEX SR 0,4 MG:
Olyfgroen ondeursigtig/oranje ondeursigtig, grootte 2, harde gelatien kapsules wat vryvloeiende wit tot naaswit sferoïede bevat, met "CL 23" op die doppie en "0.4" op die liggaam met swart ink gedruk.

Stulpverpakking:
Kapsules word verpak in deursigtige film PVC/PE/PVdC, 250 µ /25 µ/90 GSM as vormingsmateriaal en gewone silwerkleurige aluminiumfoelie, 25 µ, 6-8 GSM as dekmateriaal.
Verpakkingstgrootte: 30's

HDPE houer verpakking:
Kapsules word verpak in 30 cc, ronde wit HDPE bottel met 28-400 nekafwerking, toegemaak met 'n wit 28 mm kinderbestande sluiting met pulp en hitte-seëlvoering.
Verpakkingsgrootte: 30's
Nie alle verpakkings en verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat en Vervaardiger
MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia-rylaan 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid-Afrika.

Hierdie inligtingstuk was laas hersien in
04 August 2022

Registrasienommer
PRAVLEX SR 0,4 MG: 48/34/0855

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.

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: PRAVLEX SR 0,4 MG (Tamsulosin hydrochloride 0.4 mg SR Capsules)	
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: 400 (L) x 335 (W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM03986001**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 32132 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: NA**
15. Revision no: 00	**16. A/W File name: Y:\Tamsulosin 0.4 mg capsules\SA Private Market\Tamsulosin hydrochloride 0.4 mg SR Capsules PI & PIL - PM03986001.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	Vanita Rajool Digitally signed by Vanita Rajool DN: cn=Vanita Rajool, o=Macleods Pharmaceuticals SA (Pty) Ltd., ou=Responsible Pharmacist, email=vanitar@macleodspharma.com, c=ZA Date: 2022.10.31 21:12:34 +02'00'				

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 Release Date	Artwork Implementation Date
1) New Artwork for South Africa Private Market	PM03986001		