SCHEDULING STATUS:

S4

1. NAME OF THE MEDICINE

BENIPROSIN SR

Tamsulosin hydrochloride 0,4 mg (capsules)

Sugar free

Read all of this leaflet carefully before you start taking BENIPROSIN SR

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

1.WHAT BENIPROSIN SR IS AND WHAT IT IS USED FOR

BENIPROSIN SR capsules contains tamsulosin hydrochloride 0,4 mg

BENIPROSIN SR capsules are indicated for the treatment of functional symptoms of benign prostatic hyperplasia (BPH).

2.WHAT YOU NEED TO KNOW BEFORE YOU TAKE BENIPROSIN SR

Do not take BENIPROSIN SR :

- If you are hypersensitive (allergic) to tamsulosin hydrochloride or any of the other ingredients of BENIPROSIN SR.
  Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you suffer from dizziness when you want to sit up or stand up from the lying position
- If you suffer from serious infection of the liver.
- If you have a history of fainting while urinating or right after urinating
- If you are using in combination with ketoconazole (a strong CYP3A4 inhibitor) used to treat fungal infections

Do not take BENIPROSIN SR if any of the above applies to you.

If you are not sure, talk to your doctor or pharmacist before receiving BENIPROSIN SR. Do this even if they have applied in the past

Warnings and precautions

BENIPROSIN SR capsules are intended for male patients only

Take special care with BENIPROSIN SR :

- If you have a decrease in blood pressure with orthostatic hypotension (dizziness, weakness) and temporary loss of consciousness which may occur during treatment with BENIPROSIN SR**.** At the first signs of orthostatic hypotension (dizziness, weakness), the patient should sit or lie down until the symptoms have disappeared
- If you should be examined in order to exclude the presence of other conditions, which can cause the same symptoms as an enlarged prostate before therapy with BENIPROSIN SR is iniated

- If digital rectal examination, and when necessary, determination of prostate specific antigen (PSA) should be performed before treatment and at regular intervals afterwards
- If intraoperative Floppy Iris Syndrome (IFIS) (variant of small pupil syndrome) has been observed during cataract surgery in some patients previously treated with tamsulosin hydrochloride. Discontinuing tamsulosin hydrochloride 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
- If you are planning to undergo cataract or glaucoma surgery, please inform your doctor that you are taking or recently have taken BENIPROSIN SR

The benefit of stopping BENIPROSIN SR therapy prior to cataract surgery has not been established

Other medicines and tamsulosin capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Other medicines may be affected by BENIPROSIN SR, They , in turn may affect how well BENIPROSIN SR works

BENIPROSIN SR can interact with cimetidine which increases plasma levels of tamsulosin and concomitant administration with furosemide decreases the plasma levels of tamsulosin, but as levels remain within the normal range, dosage need not be changed

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

Concurrent administration of other alpha1-adrenoceptor antagonists could lead to hypotensive(decrease in blood pressure) effects

Fertility, pregnancy and lactation BENIPROSIN SR capsules should not be used in females.

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

Driving and using machines

Dizziness which may affect the ability to drive or operate machinery may occur.

Make sure you know how you react to BENIPROSIN SR before you drive, use machines, or engage in any other activity that could be dangerous if you are not alert.

3.HOW TO TAKE BENIPROSIN SR:

Taking your medicine:

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

Always take BENIPROSIN SR exactly as your doctor has instructed you. It is important to finish a full course of treatment.

You should check with your doctor or pharmacist if you are not sure.

CAPSULES

One 0,4 mg of BENIPROSIN SR capsule to be taken daily after breakfast or after first daily meal

BENIPROSIN SR capsules should be swallowed whole with water (about 150 ml) in the standing or sitting position.

BENIPROSIN SR capsules should not be crushed or chewed, as this will interfere with the sustained release property of this active ingredient.

If you take more BENIPROSIN SR than you should:

No cases of acute over dosage have been reported. However, acute hypotension(decrease in blood pressure) could theoretically occur after over dosage in which case cardiovascular support should be given

Blood pressure can be restored and heart rate brought back to normal by lying the patient down

Measures such as vomiting, can be taken to impede absorption.

When large quantities are involved; stomach emptying can be applied and activated charcoal and an osmotic laxative, such as sodium sulphate, can be administered

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take the carton and bottle with you. This is so the doctor knows what you have taken.

If you forget to take BENIPROSIN SR:

If you forget to take BENIPROSIN SR, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose

4.POSSIBLE SIDE EFFECTS

BENIPROSIN SR can have side effects.

Not all side effects reported for BENIPROSIN SR are included in this leaflet. Should your general health worsen or if you experience any untoward effect while taking BENIPROSIN SR, please consult your doctor, pharmacist or other healthcare professional for advice.

Stop taking BENIPROSIN SR and see a doctor, or go to a hospital

- If you get swelling of the hands, feet, ankles, face, lips or throat, which may cause difficult in swallowing or breathing. You could also notice an itchy, nettle rash (urticaria).
- If you experience extremely serious allergic skin reaction (Stevens-Johnson Syndrome)

This may mean that you are having an allergic reaction to BENIPROSIN SR.

Tell your doctor if you notice any of the following:

Frequent side effects:

- dizziness
- weakness
- ejaculation disorders
- retrogade ejaculation
- ejaculation failure

Tell your doctor or pharmacist if you notice any of the following side effects

Less frequent side effects:

- headache
- temporary loss of consciousness
- low blood pressure
- irregular heartbeat

- inflammation of the membrane of the nose
- vomiting
- constipation
- nausea
- diarrhoea
- rash
- itching
- swelling of area below the skin or mucosa
- painful erections
- abnormal physical weakness or lack of energy.

Frequency unknown side effects:

- blurred vision
- visual impairment
- abnormal rhythm of the heart
- abnormal rapid heart rate
- difficulty in breathing
- nose bleeds

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 or nurse. 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 BENIPROSIN SR

5. HOW TO STORE BENIPROSIN SR

Store at or below 25 °C in the original package,

Protect from moisture

Return all unused or expired medicines to your pharmacist for safe disposal. Do not dispose of unused medicines in drains or sewage systems (e.g. toilets)

6.CONTENTS OF THE PACK AND OTHER INFORMATION

What BENIPROSIN SR contains

The active substance is tamsulosin hydrochloride

BENIPROSIN SR

Each capsule contains tamsulosin hydrochloride 0,4 mg

The other ingredients are:

Tamsulosin hydrochloride beads:

Magnesium stearate, methycrylic acid-ethyl acrylate copolymer (1:1) dispersion;microcrystalline cellulose (PH101)

Enteric coating

Methycrylic acid-ethyl acrylate copolymer(1:1), sodium hydroxide, triacetin, talc,

Extra granular

Talc

Capsule Shell

Brown cap/Orange body size 2

Body composition Brilliant blue (Cl No 42090), gelatin, poncrea 4R (Cl No 16255), quinolone yellow (Cl No 470005), sunset yellow (Cl No 15985), titanium dioxide (Cl No 77891**)**

Cap Composition

Brilliant blue(Cl No 42090), carmosine (Cl No14720), gelatin, titanium dioxide (Cl 77891), yellow iron oxide (Cl No 77891)

Printing Ink-1

Activated charcoal, alcohol (ethanol)[#], isopropyl alcohol[#], shellac

Printing Ink-2 & 3

Tekprint SW-9007 or Tekprint SW-9008

Black iron oxide (E172), butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, strong ammonia solution

[#] Used as solvent an lost during processing

WHAT BENIPROSIN SR LOOKS LIKE AND

CONTENTS OF THE PACK
BENIPROSIN SR

Brown, opaque cap/ orange opaque body, of size '2' imprinted with 'R' on cap and 'TSN400' on body in black edible ink, containing white to off-white granular beads

Cartons containing 10, 30 or 60 capsules packed in blister strips. The blister strip consists of clear, transparent film of PVC coated with PVdC with a backing of aluminium foil

Holder Of Certificate Of Registration

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