SCHEDULING STATUS
South Africa: S4
Namibia: NS2
Kenya: POM
Botswana: Schedule 2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
Flomax 0,4 SR Sustained Release Capsule

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TAKING FLOMAX 0,4 SR
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, professional healthcare provider, or your pharma
- FLOMAX 0,4 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 FLOMAX 0,4 SR CONTAINS:
The active substance is tamsulosin hydrochloride.
The other ingredients are:
Capsule content : microcrystalline cellulose, methacrylic acid - ethyl acrylate copolymer, polysorbate 80,sodium laurylsulfate, triacetin, calcium stearate, talc
Capsule shell: hard gelatin, indigotine, titanium dioxide E171, yellow iron oxide E172, red iron oxide E172
Printing ink: shellac, propylene glycol, black iron oxide E172

WHAT FLOMAX 0,4 SR IS USED FOR:
FLOMAX 0,4 SR is used in adult men for the treatment of complaints of the lower urinary tract associated with an enlarged prostatic gland (benign prostatic hyperplasia).

BEFORE YOU TAKE FLOMAX 0,4 SR:
Do not take FLOMAX 0,4 SR:
- if you are allergic (hypersensitive) to tamsulosin or to any of the other ingredients in FLOMAX 0,4 SR. Hypersensitivity may present as sudden local swelling of the soft tissues of the body (e.g. the throat or tongue), difficult breathing and / or itching and rash (angioedema).
- if you suffer from liver problems.
- if you suffer from fainting due to reduced blood pressure when changing posture (going to sit or stand up).
- if you are being treated at the same time with medicines that may decrease the removal of FLOMAX 0,4 SR from the body (for example, ketoconazole). Your doctor or pharmacist will have informed you if this is the case.
- Do not give FLOMAX 0,4 SR to children or adolescents under 18 years because it does not work in this population.

Take special care with FLOMAX 0,4 SR:
- Periodic medical examinations are necessary to monitor the development of the condition you are being treated for.
- Fainting can occur during the use of FLOMAX 0,4 SR. At the first signs of dizziness or weakness you should sit or lie down until they have disappeared.
- if you suffer from severe kidney problems, tell your doctor.
- if you are undergoing or have been scheduled for eye surgery because of cloudiness of the lens (cataract)) or increased pressure in the eye (glaucoma), please inform your eye specialist that you have previously used, are using , or are planning to use FLOMAX 0,4 SR. The specialist can then take appropriate precautions with respect to medication and surgical techniques to be used. Ask your doctor whether or not you should postpone or temporarily stop taking FLOMAX 0,4 SR when undergoing eye surgery.

Taking FLOMAX 0,4 SR with food and drink

FLOMAX 0,4 SR must be taken after breakfast or the first meal of the day.

Pregnancy and Breastfeeding
FLOMAX 0,4 SR is not for use in women.
Fertility:
In men, abnormal ejaculation has been reported (ejaculation disorder). This means that the semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure). This phenomenon is harmless.

Driving and using machinery
There is no evidence that FLOMAX 0,4 SR affects the ability to drive or to operate machinery or equipment. However, you should bear in mind that dizziness can occur, in which case you should not do things that need special attention.

Using other medicines with FLOMAX 0,4 SR:
Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines.)
Taking FLOMAX 0,4 SR together with other medicines from the same class (α 1-adrenoceptor antagonists) may cause an unwanted additional decrease in blood pressure.
It is especially important to inform your doctor if you are taking medicines which may decrease the rate at which FLOMAX 0,4 SR is broken down by the body, like erythromycin.

HOW TO TAKE FLOMAX 0,4 SR:
Do not share medicines prescribed for you with any other person.
Always take FLOMAX 0,4 SR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
Do not double the dose.
Do not share FLOMAX 0,4 SR that is prescribed for you with any other person.

The dosage is 1 capsule per day to be taken after breakfast or the first meal of each day. The capsule must be swallowed whole and not be crunched or chewed. Usually, FLOMAX 0,4 SR is prescribed for long periods of time. The effects on the bladder and on urination are maintained during long-term treatment with FLOMAX 0,4 SR.

If you take more FLOMAX 0,4 SR than you should
Taking too many FLOMAX 0,4 SR may lead to an unwanted decrease in blood pressure and an increase in heart rate, with feelings of faintness. Contact your doctor immediately if you have taken too much FLOMAX 0,4 SR.

If you forget to take FLOMAX 0,4 SR
You may take your daily FLOMAX 0,4 SR later the same day if you have forgotten to take it as recommended. If you have missed a day, just continue to take your daily capsule as prescribed. Never take a double dose to make up for the forgotten capsule.

If you stop taking FLOMAX 0,4 SR
When treatment with FLOMAX 0,4 SR is stopped prematurely, your original complaints may return. Therefore use FLOMAX 0,4 SR as long as your doctor prescribes, even if your complaints have disappeared already.
Always consult your doctor, if you consider stopping this therapy.

POSSIBLE SIDE EFFECTS:
FLOMAX 0.4 SR can have side effects.
Not all side effects reported for FLOMAX 0.4 SR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Frequent :
Dizziness, particularly when going to sit or stand up.
Abnormal ejaculation (ejaculation disorder). This means that semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure). This phenomenon is harmless.
Less frequent:
Headache, palpitations (the heart beats more rapidly than normal and it is also noticeable), reduced blood pressure e.g. when getting up quickly from a seating or lying position sometimes associated with dizziness; runny or blocked nose (rhinitis), diarrhoea, feeling sick and vomiting, constipation, weakness (aesthenia), rashes, itching and hives (urticaria).
Faintness and sudden local swelling of the soft tissues of the body (e.g. the throat or tongue) difficult breathing and / or itching and rash, often as an allergic reaction (angioedema).
Priapism (painful prolonged unwanted erection for which immediate medical treatment is required).
Rash, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (Stevens Johnson syndrome).
Abnormal irregular heart rhythm (atrial fibrillation, dysrhythmia, tachycardia), difficult breathing (dyspnoea).
Not known (frequency cannot be estimated from the available data):
Blurred vision, impaired vision
Nose bleeds (epistaxis)
Serious skin rashes (erythema multiform, exfoliative dermatitis)
Dry mouth
If you are undergoing eye surgery because of cloudiness of the lens (cataract) or increased pressure in the eye (glaucoma) and are already taking or have previously taken FLOMAX 0,4 SR, the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during the procedure.

STORING AND DISPOSING OF FLOMAX 0,4 SR:
Store below 25 °C. Protect from moisture.
Keep all medicines out of the reach of children.
Do not use FLOMAX 0,4 SR after the expiry date which is stated on the blister pack and on the carton after EXP.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). Return all unused medicine to your pharmacist.

PRESENTATION OF FLOMAX 0,4 SR:
Three blister strips of 10 capsules

IDENTIFICATION OF FLOMAX 0,4 SR:
FLOMAX 0,4 SR is a capsule with an orange body and an olive green cap with the Astellas logo, “0,4” and “701” printed in black on the capsule.

REGISTRATION NUMBER:
South Africa: 30/34/0428
Namibia: Reg. No. 06/34/0043
Kenya: CTD2117
Botswana: BOT0200514

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DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

Date of registration: 18 March 1997
Date of the most recently revised patient information leaflet as approved by the Authority: 2 June 2020

Reporting of suspected adverse reactions in Botswana:
e-Reporting: https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=BW
email: reportadr@bomra.co.bw