Module 1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

UROMAX CO 0,5/0,4 mg HARD CAPSULES

(Dutasteride 0,5 mg and tamsulosin 0,4 mg hard capsules)

Read all of this leaflet carefully before you start taking UROMAX CO:

- 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.
- UROMAX CO 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 UROMAX CO is and what it is used for.
2. What you need to know before you take UROMAX CO.
3. How to take UROMAX CO.
4. Possible side effects.
5. How to store UROMAX CO.
6. Contents of the pack and other information.

1. What UROMAX CO is and what it is used for

UROMAX CO is a combination of two medicines, namely, dutasteride and tamsulosin used to treat men with a condition called benign prostatic hyperplasia (BPH). BPH is a non-cancerous growth of the prostate gland, caused by producing too much of a hormone called dihydrotestosterone.

An enlarged prostate gland can cause urinary problems, such as difficulty in passing urine, frequent urination or slow and less forceful release of urine.

Dutasteride belongs to a group of medicine called 5-alpha reductase inhibitors and tamsulosin belongs to a group of medicine called alpha-blockers.

Dutasteride works by lowering production of the hormone dihydrotestosterone. This helps to decrease the size of the enlarged prostate gland to relief symptoms. Tamsulosin works by relaxing the muscles in the prostate gland, making it easier to pass urine and improve your condition.

2. What you need to know before you take UROMAX CO

Do not take UROMAX CO:

- If you are hypersensitivity (allergic) to dutasteride, other 5α-reductase inhibitors, tamsulosin hydrochloride, peanut or soya oil, or any of the other ingredients of UROMAX CO.
- If you suffer from low blood pressure that makes you experience dizziness, lightheadedness or even faint especially after getting up from a sitting or lying position.

- If you have severe liver disease.

UROMAX CO is indicated for use in men only. It must not be taken by women or children.

Warnings and precautions:

Take special care with UROMAX CO:

- If you have pre-existing heart disease or a history of heart-related problems
- If you have liver or kidney problems or disease
- If you are going for surgery for cataracts, your doctor or eye specialist may ask you to stop taking UROMAX CO before the operation
- If the tablets are leaking and you are a child or a woman, wash the affected area immediately with soap and water because the active ingredient can be absorbed through the skin
- When you are taking UROMAX CO and you experience low blood pressure including dizziness or fainting (orthostatic hypotension), you should lie down or sit still until there is an improvement in your condition.
- If you take medicine containing ketoconazole, erythromycin or paroxetine as it may have an influence on the effectivity of UROMAX CO
- Before taking UROMAX CO, your doctor may perform a digital rectal examination or other evaluations for prostate cancer
- If you notice unusual changes such as lumps in your breast, breast enlargement or breast discharge you should contact your doctor immediately

Other medicines and UROMAX CO:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

The following medicines may cause increased levels of tamsulosin in your blood, which may cause you to experience side effects **(see section 4)**:

- Medicines (anaesthetic medicines, PDE5 inhibitors and alpha-1 adrenergic blockers) used for lowering your blood pressure.
- Medicines for erectile dysfunction such as sildenafil, vardenafil and tadalafil.
- Cimetidine (used for heartburn and stomach ulcers).
- Ketoconazole (used to treat fungal infections of the skin and/or nails).
- Paroxetine (used in the treatment of depression and anxiety disorders).

The following medicines can lead to increased elimination of tamsulosin component of UROMAX CO, thereby making it less effective*:*

- Diclofenac (used for treating pain and inflammation).
- Warfarin (used in the treatment or prevention of blood clots, which can in turn reduce heart problems and stroke).

Tell your doctor if you are taking any of these medicines listed above as they may interfere with your UROMAX CO treatment.

UROMAX CO with food and drink:

UROMAX CO should be taken 30 minutes after the same meal each day.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Women must not take UROMAX CO.
Pregnant women or those who may be pregnant must not handle leaking capsules.
Dutasteride, contained in UROMAX CO, is absorbed through the skin and can adversely affect the male foetus by inhibiting formation of external genitals of the baby. This is a particular risk in the first 16 weeks of pregnancy.
If your partner is pregnant or may be pregnant, you must use a condom during sexual intercourse in order to avoid exposing her to UROMAX CO as dutasteride has been found in semen of men taking UROMAX CO.

UROMAX CO has been shown to reduce sperm count and sperm motility. Therefore, this can cause problems with male fertility.

You should not take UROMAX CO when you are breastfeeding.

Driving and using machines:

UROMAX CO may cause low blood pressure (symptoms like dizziness and feeling

faint) and therefore may interfere with driving and operating machinery.

It is not always possible to predict to what extent UROMAX CO may interfere with your daily activities. Ensure that you do not engage in driving or use of machinery until you are aware of the measure to which UROMAX CO affects you**.**

UROMAX CO contains lecithin soy:

Do not take UROMAX CO if you are allergic to peanut or soya oil.

3. How to take UROMAX CO

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

Always take UROMAX CO exactly as your doctor has told you. Check with your doctor if you are not sure.

- Take one capsule once daily approximately 30 minutes after the same meal each day.
- The capsules should be swallowed whole and not chewed or opened.

Your doctor will tell you how long your treatment with UROMAX CO will last. If you have the impression that the effect of UROMAX CO is too strong or too weak, tell your doctor or pharmacist.

If you take more UROMAX CO than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

If you forget to take UROMAX CO:

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

UROMAX CO can have side effects.

Not all side effects reported for UROMAX CO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking it, please consult your healthcare provider for advice.

If any of the following happens, stop taking UROMAX CO 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 and dizziness,
- flu-like symptoms, red to purple painful blisters on the skin and mucous membrane on areas like mouth, genitals, eyes and nose (Steven-Johnson syndrome).

These are all very serious side effects. If you have them, you may have had a serious reaction to UROMAX CO. 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:

- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty breathing,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems

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:

- Changes in the breast tissue such as lumps or nipple discharge (see **section 2**)
- Prolonged and painful erection
- Ejaculation disorders or abnormal ejaculation
- Altered or decreased sexual drive
- Difficulty to obtain an erection

Side effects that occur less frequently:

- Palpitations (heart beating too fast or too hard)
- Severe common cold (rhinitis)
- Constipation
- Diarrhoea

- Vomiting
- Dizziness.

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, pharmacist or nurse. This includes any possible side effects not reported in this leaflet. You can also report side effects to SAHPRA via **6.04 Adverse Drug Reaction Reporting Form,** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or to Cipla Medpro (Pty) Ltd (by e-mail: drugsafetysa@cipla.com. By reporting side effects, you can help provide more information on the safety of UROMAX CO.

5. How to store UROMAX CO

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Use within 90 days of opening.

Avoid contact with leaking capsules. Dutasteride is absorbed through the skin. If contact is made with leaking capsules, the area should be washed immediately with soap and water.

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 UROMAX CO contains:

The active substances per hard capsule are dutasteride 0,5 mg and tamsulosin 0,4 mg.

The other ingredients are butylhydroxytoluene, calcium stearate, cellulose microcrystalline, colloidal hydrous silica, dibutyl sebacate, gelatin capsule, glycerol, methacrylic acid-ethyl acrylate copolymer (1:1), polypropylene glycol, polysorbate 80 and titanium dioxide.

The contents of hard-shell gelatin capsule are black iron oxide, gelatin, potassium hydroxide, propylene glycol, red iron oxide, Shellac, strong ammonia solution, titanium dioxide and yellow iron oxide.

Contains antioxidant and preservative: butylhydroxytoluene 0,006 % *w/w*

What UROMAX CO looks like and contents of the pack:

UROMAX CO hard capsules are oblong hard gelatine capsules, Nº 0EL, of approximately 24,2 mm x 7,7 mm, body of brown colour and cap of beige colour with black code C001 on the cap. Each capsule contains:

- One oblong soft gelatine capsule of Dutasteride (approximately 16,5 x 6,5 mm) of light yellow colour, filled with transparent liquid.
- Approximately 183,8 mg of modified release tamsulosin pellets with white to off-white colour.

UROMAX CO is marketed in HDPE bottles that are fitted with silica gel desiccant-containing polypropylene caps in the following packs:

- 7 hard capsules in 35 ml bottle
- 30 hard capsules in 100 ml bottle
- 90 hard capsules in 250 ml bottle

Holder of certificate of registration and manufacturer:

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