MODULE 1.3.2: APPROVED PATIENT INFORMATION LEAFLET

Information for the Patient about

UROMAX (MODIFIED RELEASE CAPSULES)

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

UROMAX containing 0,4 mg **tamsulosin hydrochloride** (Modified release capsules).

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

- **Keep this leaflet, you may need to read it again.**
- **If you have further questions, please ask your doctor or pharmacist.**
- **UROMAX 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 UROMAX CONTAINS:

The active ingredient is tamsulosin hydrochloride.

Each capsule contains 0,4 mg tamsulosin hydrochloride equivalent to 0,367 mg tamsulosin in a modified release pellet formulation.

The inactive ingredients are colloidal anhydrous silica, Eudragit L30 D-55, hypromellose (HPMC E-15 and HPMC 6 cps), polysorbate 80, propylene glycol, purified talc, sugar spheres, Surelease E-7-7050, triethyl citrate and hard gelatine

capsules.

Contains sugar (sucrose).

WHAT UROMAX IS USED FOR:

UROMAX causes smooth muscles in the bladder neck and prostate to relax, resulting in an improvement in urine flow rate and reduction in the symptoms of an enlarged prostate gland (benign prostatic hyperplasia – BPH).

BEFORE YOU TAKE UROMAX:

Do NOT take UROMAX:

- If you are allergic (hypersensitive) to tamsulosin hydrochloride or to any of the inactive ingredients of **UROMAX**.
- If you have a history of orthostatic hypotension (low blood pressure upon standing up).
- If you have severe liver function impairment.
- If you are receiving treatment with ketoconazole, an antifungal medicine (see **"Taking other medicines with UROMAX"**).
- If you are a female, breastfeeding or a child.

Take special care with UROMAX:

UROMAX is intended for use in males only.

Treatment with **UROMAX** may cause a decrease in blood pressure followed by low blood pressure upon standing up (orthostatic hypotension) and fainting. If you should

experience dizziness or weakness upon standing up, you should sit or lie down until the symptoms have disappeared.

Before your doctor starts your treatment with **UROMAX** you will be examined to exclude other conditions that may cause symptoms similar to an enlarged prostate gland (benign prostatic hyperplasia). Digital rectal examination, and possibly determination of prostate specific antigen (PSA) will be performed before you start treatment and at regular intervals thereafter.

Tell your doctor if you have been diagnosed with kidney function impairment as you may require special monitoring.

If you are scheduled to undergo cataract surgery (to remove a cloudy lens of the eye) or glaucoma surgery (to relieve pressure inside the eye) while you are taking **UROMAX** or if you have previously taken **UROMAX**, please advise your doctor or surgeon before your surgery. You may have an increased risk of developing complications during or after such surgeries, called intraoperative floppy iris syndrome (IFIS) (see **"POSSIBLE SIDE-EFFECTS"**). This may cause your iris (the coloured part of your eye) to become floppy and lead to your pupil (the black part of your eye) not widening or constricting normally during surgery.

Although some reports suggest that **UROMAX** should be stopped 1 – 2 weeks before cataract or glaucoma surgery, the benefit and duration of interruption of treatment before surgery has not yet been established. IFIS has also been reported in patients who had stopped **UROMAX** for longer than 2 weeks before surgery.

Ejaculation disorders have been observed in men on short-term and long-term treatment with **UROMAX**. Ejaculation disorders such as retrograde ejaculation (when semen is redirected into the bladder instead of out through the urethra) and ejaculation failure have been reported.

Taking UROMAX with food and drink:

UROMAX should be taken daily after breakfast (see **"HOW TO TAKE UROMAX"**).

To avoid interference with the modified release property of **UROMAX**, it should be swallowed whole with water (about 150 mℓ) while standing or sitting and should not be crunched or chewed.

Pregnancy and breastfeeding:

UROMAX should not be taken by women.

Driving and using machinery:

UROMAX may cause you to feel dizzy, drowsy and faint and to have blurred vision. It may therefore affect your ability to drive or operate machinery. Do not drive or operate machinery until you know how **UROMAX** affects you.

Important information about some of the ingredients of UROMAX:

UROMAX contains sugar (sucrose) which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **UROMAX**.

Taking other medicines with UROMAX:

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

Please inform your doctor if you are taking any of the following medicines, as you may require a reduction in dose or special precautions:

- Ketoconazole, an antifungal medicine (see **"Do NOT take UROMAX"**).
- Erythromycin, an antibiotic.
- Diclofenac, used in the treatment of pain, swelling and inflammation.
- Warfarin, a blood thinner.
- Other alpha$_1$-adrenoceptor blockers, including doxazosin for treatment of an enlarged prostate gland, or prazosin used for high blood pressure.
- Paroxetine, used in the treatment of depression.

HOW TO TAKE UROMAX:

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

Always take UROMAX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Take one 0,4 mg **UROMAX** capsule daily after breakfast.

The capsule should be swallowed with water (about 150 mℓ) in the standing or sitting position. The capsule should not be chewed or crunched as this may interfere with the sustained release of the active ingredient in **UROMAX** (see **"Taking UROMAX with food and drink"**).

Your doctor will tell you how long your treatment with **UROMAX** will last. Do not stop treatment early because this may affect symptoms of your enlarged prostate gland.

If you have the impression that the effect of **UROMAX** is too strong or too weak, tell your doctor or pharmacist.

If you take more UROMAX than you should:

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

If you forget to take UROMAX:

Always take **UROMAX** as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose.

POSSIBLE SIDE-EFFECTS:

UROMAX can have side-effects.

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

If any of the following happens, stop taking **UROMAX** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions, which may include a skin rash, itching and hives, difficult breathing, wheezing, or swelling of the face, lips, or tongue (which may be life-threatening).
- Any skin rash with blister formation (which may be life-threatening).
- Difficult breathing.

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

- Those that occur less frequently:
    - Fainting spells.
    - Persistent and painful erection (priapism).
- Those that occur with unknown frequency:
    - Eye problems including blurred vision and visual impairment during or after cataract or glaucoma surgery, called intraoperative floppy iris syndrome (see **"Take special care with UROMAX"**).
    - Fast or irregular heartbeat, dizziness, light-headedness, shortness of breath, chest pain, fainting spells (atrial fibrillation).
    - Inflamed blisters on the skin (erythema multiforme), a scaling, crusting skin rash (exfoliative dermatitis).

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

Tell your doctor if you notice any of the following:

- Those that occur frequently:
    - Dizziness.
    - Abnormal ejaculation, including retrograde ejaculation (when semen is redirected into the bladder instead of out through the urethra) and ejaculation failure.
- Those that occur less frequently:
    - Headache.
    - Pounding heartbeat (palpitations).
    - Low blood pressure upon standing up, including dizziness and weakness (orthostatic hypotension).
    - Runny nose, sneezing (rhinitis).
    - Constipation, nausea, vomiting, diarrhoea (loose stools).
    - Rash, itching, hives.
    - General feeling of weakness, tiredness (asthenia).
- Those that occur with unknown frequency:
    - Drowsiness.
    - Swelling of the lower legs or ankles (oedema).
    - Nose bleeds.
    - Dry mouth.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF UROMAX:

Store at or below 25 °C.

Protect from excessive heat, freezing and moisture.

Keep the blister strips in the outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF UROMAX:

PVC/PVDC/Aluminium foil blister strips of 10 capsules packed in 30’s.

IDENTIFICATION OF UROMAX:

White to off-white pellets filled in size “2” hard gelatine capsules with brown cap and off-white opaque body.

REGISTRATION NUMBER:

A40/34/0046

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD.

Parc du Cap

Mispel Street

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DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:

18 April 2008

Revised: 28 November 2019