PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

Schedule 4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

OMSAL CAPSULES. Each modified release capsule contains 0,4 mg tamsulosin hydrochloride.

Please read this leaflet carefully before you start using OMSAL CAPSULES.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **OMSAL CAPSULES** 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.

1. WHAT OMSAL CAPSULES CONTAINS:

Each capsule contains 0,4 mg tamsulosin hydrochloride as the active ingredient. The other inactive ingredients are calcium stearate, triethyl citrate, purified talc, methacrylic acid copolymer dispersion, polysorbate 80, sodium laurilsulfate, microcrystalline cellulose and purified water filled in an empty hard gelatine capsule shell size “2” with standard brown opaque cap and buff opaque body.

2. WHAT OMSAL CAPSULES ARE USED FOR:

Tamsulosin, the active ingredient of **OMSAL CAPSULES**, is used to treat the signs and

symptoms of benign enlargement of the prostate (BPH). Benign enlargement of the prostate is a problem that can occur in men as they get older. The prostate gland is located below the bladder. As the prostate gland enlarges, certain muscles in the gland may become tight and get in the way of the tube that drains urine from the bladder. This can cause problems in urinating.

OMSAL CAPSULES help relax the muscles in the prostate and the opening of the bladder. This may help to increase the flow of urine and/or decrease the symptoms of BPH.

3. BEFORE YOU USE OMSAL CAPSULES:

Do not take OMSAL CAPSULES:

- If you are hypersensitive (allergic) to tamsulosin or any of the other ingredients contained in **OMSAL CAPSULES**.
- If you have problems with your liver.
- If you have a history of feeling dizzy or fainting when you get up from a lying or sitting position (orthostatic hypotension).
- If you are taking a medicine containing the active ingredient ketoconazole which is used to treat fungal infections.

Take special care with OMSAL CAPSULES:

- Tell your doctor if you are going to have cataract eye surgery while using **OMSAL CAPSULES**.
- If you have problems with your kidneys.

Taking OMSAL CAPSULES with food or drink

The capsule should be swallowed whole with a glass of water. Do not chew or crush the contents of these capsules. The capsules should be taken after breakfast or the first meal of the day.

Pregnancy and breastfeeding

OMSAL CAPSULES is intended for use in males only. It is not yet known if this medicine is safe for pregnant women or mothers that breast-feed their babies.

Driving and using machinery:

OMSAL CAPSULES can cause dizziness, light headedness and headaches. *Do not drive or operate any machinery until you know how* **OMSAL CAPSULES** *will affect your ability to drive or concentrate.*

Taking other medicines with OMSAL CAPSULES:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking any of the following:

- Alpha blockers such as prazosin, doxazosin, phentolamine or terazosin (medicines used for high blood pressure, BPH which affects the prostate gland or Raynaud's disorder which is a condition that causes some areas of your body to feel cold in response to cold temperatures or stress.)
- Cimetidine (medicine for ulcers or heartburn).
- Furosemide (medicine that reduce water retention in the body - diuretic).
- Diclofenac (anti-inflammatory medicine.)
- Warfarin (medicine that prevent the blood from clotting).
- Ketaconazole (medicines to treat fungal infections).

Not all the medicines that would interact with OMSAL CAPSULES are listed above.

4. HOW TO USE OMSAL CAPSULES:

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

Always take **OMSAL CAPSULES** exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

The dose of **OMSAL CAPSULES** might be different for different patients. The number of doses you take each day, the time allowed between doses, and the length of time you take **OMSAL CAPSULES** depend on the medical problem for which you are taking **OMSAL CAPSULES.** Your doctor will tell you how long your treatment with **OMSAL CAPSULES** will last.

OMSAL CAPSULES, unless otherwise prescribed, should be used as follows:

OMSAL CAPSULES is intended for male patients only.

The dosage is one **OMSAL CAPSULES** daily, to be taken after breakfast or the first meal of the day. The dosage should be taken at the same time each day. Swallow the capsule whole and do not crush or chew the capsule.

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

If you have taken more OMSAL CAPSULES 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.

You may experience severe dizziness and light-headedness which may occur due to a possible fall in your blood pressure. Take this leaflet and the rest of the remaining capsules with you so the doctor will know what you have taken.

If you forget to take your OMSAL CAPSULES:

Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next capsules at the usual time. **Do not take a double dose to make up for forgotten individual doses.**

5. POSSIBLE SIDE-EFFECTS:

OMSAL CAPSULES can have side-effects. Not all side effects reported for **OMSAL CAPSULES** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

The following side-effects may occur.

If you experience the following side-effects contact your doctor immediately as you may need urgent medical attention:

- Pancreatitis (inflammation of the pancreas) which can cause pain in your abdominal area.
- Skin rash and swelling of the throat and lips as this may indicate that you are allergic to **OMSAL CAPSULES.**
- Steven-Johnson syndrome which is a skin reaction which results in a painful red or purple rash which spreads and creates blisters.

Check with your doctor if any of the following side-effects continue or are bothersome.

These side-effects have been reported frequently:

- Headache
- Dizziness
- Stuffy or runny nose
- Abnormal ejaculation
- Unusual weakness

These side-effects have been reported less frequently:

- Chest pain
- Difficulty in sleeping
- Drowsiness
- Nausea, vomiting

- Constipation or diarrhoea
- Decreased sexual desire or drive.
- Blurred eye sight
- Breathlessness
- Nose bleeding
- Burning and prickling sensation
- Ringing and buzzing in the ears
- Joint pain
- Sweating more than usual
- Feeling faint
- Dry mouth

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

6. STORING AND DISPOSAL OF OMSAL CAPSULES:

Store all medicines out of reach of children.

Store at or below 25 ºC. Protect from moisture.

Do not store the capsules in the bathroom.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF OMSAL CAPSULES:

OMSAL CAPSULES are packed in clear transparent PVC/PVDC, plain aluminium foil blister strips. Each blister strip will contain 10 capsules. Three blister strips each containing 10 capsules will be placed in an outer carton.

8. IDENTIFICATION OF OMSAL CAPSULES:

White or off white pellets filled in size '2' empty hard gelatine capsules with standard brown cap and buff opaque body.

9. REGISTRATION NUMBER:

42/18.10.0538

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Acino Pharma (Pty) Ltd

106 16th Road

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11. DATE OF PUBLICATION:

7 December 2012

Namibia

Scheduling Status: NS2

Reg. No.: 14/18.10/0039