

Proprietary name:	UROTAL
Dosage form:	Capsules
Active Ingredient:	Tamsulosin hydrochloride
Strength per dosage unit:	0,4 mg per capsule

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Urotal 0,4 mg (capsules)

Sugar free

Please read this leaflet carefully before taking Urotal.

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

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1. WHAT UROTAL IS AND WHAT IT IS USED FOR

Urotal acts by relaxing the muscles in the prostate and urethra (the tube that carries urine to the outside), and lets urine pass more readily through the urethra and assist with urination.

In the prostate gland, bladder, and urethra there are specialised cells containing α_{1A} -receptors that cause the muscles in the urethra to tighten. **Urotal** is an α_{1A} -adrenoceptor blocker, which reduces the action of these specialised cells and relaxes the muscles making it easier to pass water.

Urotal is used in men to treat the symptoms associated with benign prostatic hyperplasia (BPH) which is enlargement of the prostate. These symptoms include difficulty in starting to pass water, frequent trips to the toilet to pass water, a feeling of not completely emptying the bladder and having to get up several times in the night to pass water.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE UROTAL:

Do not take Urotal if:

- you are allergic (hypersensitive) to tamsulosin or any of the other ingredients of **Urotal**,
- you have a severe liver condition,
- you have ever fainted or felt dizzy when suddenly sitting or standing up. Dizziness can sometimes occur when taking **Urotal**, particularly if you are also taking other α_1 -blockers (medicine used to treat high blood pressure). If you do feel weak or dizzy make sure you sit or lie down straight away until the symptoms have disappeared,
- you are on medicines which block the function of an important enzyme (CYP3A), used to help the body get rid of toxins. Examples of such medicines are ketoconazole (used to treat fungal infections), antiretroviral medicines (used to treat HIV), erythromycin (used to treat bacterial infection).

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Do not take Urotal if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking **Urotal**.

Take special care with Urotal:

Tell your doctor or your healthcare provider before taking **Urotal**:

- If you have low blood pressure that happens when you are standing up from sitting or lying down (orthostatis),
- If you have serious liver problems,
- 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 tamsulosin hydrochloride. The specialist can then take appropriate precautions with respect to medicine and surgical techniques to be used. Ask your doctor whether or not you should postpone or temporarily stop taking this medicine when undergoing eye surgery because of a cloudy lens (cataract) or increased pressure in the eye (glaucoma),
- If you are taking medicines such as ketoconazole (medicine used to treat fungal infection), erythromycin (medicine used to treat bacterial infection), cimetidine (medicine used to treat ulcer), medicines used to treat high blood pressure, warfarin (medicine used to thin the blood),
- **Urotal** can lead to a prolonged, painful erection of the penis for longer than usual,
- Patients likely to have prostate cancer and enlarged prostate must be screened before taking **Urotal**.
- If you are allergic to antibiotics containing sulfa, such as sulfonamide (medicine used treat infections).

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Other medicines and Urotal:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

The use of **Urotal** with the following medicines may cause undesirable interactions:

- medicines to lower your blood pressure such as nifedipine, atenolol and enalapril,
- medicines to treat HIV such as ritonavir or indinavir,
- medicines to treat a fungal infection such as ketaconazole or itraconazole,
- other alpha blockers such as doxazosin, indoramin, prazosin or alfuzosin,
- erythromycin, an antibiotic used to treat infections,
- medicines used to treat ulcers such as cimetidine,
- medicines used to treat blood clots, such as warfarin,
- medicines used to treat pain such diclofenac,
- medicines used to treat certain heart condition such as digoxin,
- medicines used to treat lung diseases (asthma, bronchitis) such as theophylline,
- medicines used to treat diabetes such as furosemide

Please inform your doctor that you are on **Urotal** before any operation or dental procedure as there is a potential that your medicine may interfere with the effects of the anaesthetic.

Not all the medicines that may interact with Urotal are listed above.

Taking Urotal with food and drink:

Urotal should be taken after food, particularly after breakfast or first meal of the day.

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Pregnancy, breastfeeding and fertility

Urotal is not indicated for use in women.

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 machines

Urotal can have side effects such as dizziness and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

3. HOW TO TAKE UROTAL

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

Always take **Urotal** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

For adults and the elderly, the dose is one capsule per day to be taken after breakfast or the first meal of each day. Swallow the capsule whole. Do not crunch or chew. Your doctor may want to examine you from time to time whilst you are taking **Urotal**.

If you take more Urotal than you should:

If you take more **Urotal** capsules than you should, you will feel dizzy and faint due to the low blood pressure that the **Urotal** may cause.

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

If you forget to take Urotal:

You may take your capsule later the same day if you have forgotten to take it earlier. If you have missed a day, just continue to take your daily capsule from the next day. Do not take a double dose to make up for a missed dose.

If you have any further questions on the use of **Urotal**, ask your doctor or pharmacist.

If you stop taking Urotal:

Do not stop taking **Urotal** unless your doctor or pharmacist tells you to stop.

4. POSSIBLE SIDE EFFECTS

Urotal can have side effects.

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

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

- Swelling of the face, throat or tongue with breathing problems linked to allergy,
- Serious skin rashes (erythema multiform, dermatitis exfoliative), rash, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (Stevens-Johnson syndrome), itching, redness,
- Fainting (syncope)

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

Less frequent side-effects:

- Chest pain
- Palpitations (rapid or irregular heartbeat), difficult breathing (dyspnoea), abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia)

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:

- dizziness, drowsiness, sluggishness (lethargy)
- 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 side-effects:

- Abnormal physical weakness, headache, depression (persistent feeling of sadness), nervousness, sleeping problems, hallucinations,
- Dizziness as you sit or stand up,
- Runny or blocked nose, inflammation of the nasal mucous membrane due to virus infection (rhinitis), nose bleeds (epistaxis),
- tingling sensation, ringing in the ears,

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- Gastro-intestinal symptoms such as nausea and vomiting (feeling or being sick), diarrhoea or constipation, and inflammation of the pancreas,
- Persistent painful erection usually unrelated to sexual activity,
- Abnormal sweating, hair loss (alopecia) and joint pain,
- Reddened eyes, complication during lens (cataract) surgery

Frequency not known:

- blurred vision, impaired vision
- dry mouth

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

5. HOW TO STORE UROTAL

Store at or below 25 °C (Room temperature).

Store in the original package. Keep the container in the outer carton.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton and the blister.

Do not throw away any medicines in drains or sewage systems.

Return all unused medicine to the pharmacist.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Urotal contains:

The active substance: 0,4 mg of tamsulosin (as hydrochloride).

The other ingredients are: calcium stearate, hypromellose, microcrystalline cellulose, methacrylic acid polymer dispersion (Eudragit L30D-55), talc and triacetin.

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Capsules content: gelatine, FD & C Blue No.2, iron oxide red, iron oxide yellow and titanium dioxide.

What Urotal looks like and contents of the pack:

White to off white pellets filled in hard gelatin capsule size "1" Olive green opaque cap & orange opaque body imprinted with "TAM" on cap and "0.4 mg" on body in black ink.

Urotal is packed in aluminium-aluminium blister strips of 10 tablets packed into a printed cardboard carton.

Holder of certificate of registration

Alkem Laboratories (Pty) Ltd.

R21 Corporate Park,

121 Sovereign Drive, Block A, Office 202

Irene Ext. 30, Centurion, 0157

This leaflet was last revised in

Application Numbers:

Urotal: 530058.057

Access to the corresponding Professional Information

The professional information will be included in each unit pack of the product.