

TAMSULOSIN 0,4 BIOTECH
(Each capsule contains 0,4 mg tamsulosin hydrochloride
42/18.10/0478— registered)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

TAMSULOSIN 0,4 BIOTECH, 0,4 mg sustained release capsules

Tamsulosin hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking TAMSULOSIN 0,4 BIOTECH:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TAMSULOSIN 0,4 BIOTECH 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.
- If side effects get serious or you notice side effects not listed, please tell your doctor.

What is in this leaflet

1. What TAMSULOSIN 0,4 BIOTECH is and what it is used for
2. What you need to know before you take TAMSULOSIN 0,4 BIOTECH
3. How to take TAMSULOSIN 0,4 BIOTECH
4. Possible side effects
5. How to store TAMSULOSIN 0,4 BIOTECH
6. Contents of the pack and other information

1. What TAMSULOSIN 0,4 BIOTECH is and what it is used for

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Your medicine is in the form of a modified release hard capsule. This means that the capsule releases the drug slowly into the body.

TAMSULOSIN 0,4 BIOTECH capsules contain tamsulosin hydrochloride, which belongs to a group of medicine called alpha-blockers.

It reduces tension of the smooth muscles in the prostate and the urethra, enabling urine to pass more readily through the urethra and facilitating urination. In addition, it diminishes sensations of urge.

TAMSULOSIN 0,4 BIOTECH can be given to men suffering from an enlarged prostate gland (benign prostatic hyperplasia), because it relaxes the muscles allowing urine to be passed more easily.

2. What you need to know before you take TAMSULOSIN 0,4 BIOTECH**Do not take TAMSULOSIN 0,4 BIOTECH if:**

- you are allergic to tamsulosin hydrochloride or any of the other ingredients of TAMSULOSIN 0,4 BIOTECH (listed in section 6).
- you suffer or have suffered in the past from dizziness on standing up caused by low blood pressure.
- you have liver problems.
- you are using it in combination with ketoconazole (a strong CYP3A4 inhibitor) used to treat fungal infections.

Warnings and precautions

Take special care with TAMSULOSIN 0,4 BIOTECH:

- if you have severe kidney problems.
- if you have a decrease in blood pressure with orthostatic hypotension (dizziness, weakness) and temporary loss of consciousness which may occur during treatment with TAMSULOSIN 0,4 BIOTECH. At the first

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signs of orthostatic hypotension (dizziness, weakness), the patient should sit or lie down until the symptoms have disappeared.

- if you should be examined in order to exclude the presence of other conditions, which can cause the same symptoms as an enlarged prostate before therapy with TAMSULOSIN 0,4 BIOTECH is initiated.
- if digital rectal examination, and when necessary, determination of prostate specific antigen (PSA) should be performed before treatment and at regular intervals afterwards.
- if intraoperative Floppy Iris Syndrome (IFIS) (variant of small pupil syndrome) has been observed during cataract surgery in some patients previously treated with tamsulosin hydrochloride. Discontinuing tamsulosin hydrochloride 1 to 2 weeks prior to cataract or glaucoma surgery is anecdotally considered helpful, but the benefit of treatment discontinuation has not yet been established.
- if you have to go for a cataract operation. Inform your ophthalmologist if you are using TAMSULOSIN 0,4 BIOTECH at present and/or in the past. The ophthalmologist will adapt your medication accordingly and will also advise you if you should temporarily stop or postpone taking this medicine.

Make sure that you inform your doctor if any of the above apply to you. Periodic medical examinations are necessary to monitor the development of the condition you are being treated for.

Other medicines and TAMSULOSIN 0,4 BIOTECH

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

- TAMSULOSIN 0,4 BIOTECH can interact with cimetidine which increases plasma levels of tamsulosin and concomitant administration with furosemide decreases the plasma levels of tamsulosin, but as levels remain within the normal range, dosage need not be changed.
- Diclofenac and warfarin, however, may increase the elimination rate of tamsulosin.

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- Concurrent administration of other alpha1-adrenoceptor antagonists (e.g., doxazosin) and anaesthetic medicines could lead to hypotensive (decrease in blood pressure) effects.

Pregnancy, breastfeeding and fertility

TAMSULOSIN 0,4 BIOTECH is contraindicated for use in females.

Fertility

Ejaculation disorders have been observed in short and long term clinical studies with tamsulosin. Events of ejaculation disorder, retrograde ejaculation and ejaculation failure have been reported.

Driving and using machines

Do not drive or operate machines if you feel dizzy, drowsy, or have blurred vision while taking this medicine.

It is not always possible to predict to what extent TAMSULOSIN 0,4 BIOTECH may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TAMSULOSIN 0,4 BIOTECH affects them.

3. How to take TAMSULOSIN 0,4 BIOTECH**Dosage:**

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

Always take TAMSULOSIN 0,4 BIOTECH exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one capsule after breakfast or after the first meal of the day.

Swallow the capsule whole with a glass of water in the standing or sitting position.

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Do not chew the capsules (if needed, the capsules can be opened, and the contents swallowed without chewing as this would interfere with the sustained release property of the active ingredient).

If you have the impression that the effect of TAMSULOSIN 0,4 BIOTECH is too weak or too strong, tell your doctor or pharmacist.

If you take more TAMSULOSIN 0,4 BIOTECH than you should

Taking more TAMSULOSIN 0,4 BIOTECH may lead to unexpected drop of blood pressure and rapid heartbeat, followed by dizziness.

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

If you take too much of your medicine, immediately contact your doctor or nearest casualty department. Take any remaining capsules and the container with you.

If you forget to take TAMSULOSIN 0,4 BIOTECH

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

If you have forgotten to take your medicine after the first meal of the day, it can be taken later the same day. The dose can be skipped if you do not realise until the following day that you forgot to take it. Please ensure that you have enough medicine before going on holiday or a journey.

4. Possible side effects

TAMSULOSIN 0,4 BIOTECH can have side effects.

Not all side effects reported for TAMSULOSIN 0,4 BIOTECH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking while taking TAMSULOSIN 0,4 BIOTECH, please consult your healthcare provider for advice.

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If any of the following happens, stop taking / using TAMSULOSIN 0,4 BIOTECH and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the lips, tongue or face, difficulty breathing or swallowing,
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to TAMSULOSIN 0,4 BIOTECH. 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:

- A severe inflammatory eruption of the skin and mucous membranes, which is an allergic reaction to medicines or other substances called Stevens-Johnson syndrome.

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
- Abnormal ejaculation
- Retrograde ejaculation
- Ejaculation failure

Less frequent side effects:

- Headache
- Racing irregular heartbeat, fainting
- Low blood pressure - especially when sitting or standing up
- Runny nose

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- Nausea, vomiting, diarrhoea and constipation
- Allergic reactions (rash, itching, nettle rash)
- Priapism, (painful, persistent, involuntary erection of the penis), in which case immediate medical aid is needed
- Feeling of weakness

Frequency unknown side effects:

- Blurred vision
- Visual impairment
- Nose bleeds
- Dry mouth
- Skin disorder characterised by bull's-eye-shaped lesions
- Peeling of the skin over large areas of the body

If you notice any of the 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. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of TAMSULOSIN 0,4 BIOTECH.

5. How to store TAMSULOSIN 0,4 BIOTECH

Store all medicines out of the reach of children.

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Store capsules in original packaging, at or below 25 °C. Keep the blisters in the carton until required for use.

Protect from moisture - do not store in bathrooms.

Do not use the product after the use-by date on the pack (indicated as “EXP.”)

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems.

6. Contents of the pack and other information**What TAMSULOSIN 0,4 BIOTECH contains:**

The active substance is tamsulosin hydrochloride. Each modified release capsule contains 0,4 mg tamsulosin hydrochloride.

The other ingredients are methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 % (Eudragit L 30 D-55), microcrystalline cellulose, polyacrylate dispersion 30 % (Eudragit NE 30 D), polysorbate, sodium lauryl sulphate, talc.

Capsule composition:

Body: gelatin, red iron oxide (E172), titanium dioxide (E171), yellow iron oxide (E172).

Cap: black iron oxide (E172), gelatin, patent blue V (E131), titanium dioxide (E171), yellow iron oxide (E172).

Black ink: black iron oxide (E172), butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, purified water, shellac, strong ammonia sol.

What TAMSULOSIN 0,4 BIOTECH looks like and contents of the pack

TAMSULOSIN 0,4 BIOTECH capsules are yellow (body) and light-green (cap) in colour. The mark ‘TML 0,4’ is printed on the capsule in black. The capsules contain white to slightly yellowish pellets.

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TAMSULOSIN 0,4 BIOTECH capsules are available in blister strips with a silver aluminium side and a clear PVDC/TE/PVC side. The blister strips are packed in cartons. The cartons contain 10, 30, 60 or 100 capsules. All sizes may not be marketed at one time.

Holder of Certificate of Registration

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