

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Tamsulosina Baldacci 0.4 mg extended-release capsules  
0.4 mg hydrochloride de tamsulosin

Read this leaflet carefully before you start taking this medicine, as it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you are not sure, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. You should not give it to others. The medicine can be harmful to them even if they show the same signs of illness.
- If you get any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist.

What's in this leaflet:

1. What Tamsulosin Baldacci 0.4 mg extended-release capsules is and what it is used for
2. What you need to know before you take Tamsulosin Baldacci 0.4 mg extended-release capsules
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1. What Tamsulosin Baldacci 0.4 mg extended-release capsules is and what it is used for

The active substance in Tamsulosin Baldacci extended-release capsules is tamsulosin. This is a selective  $\alpha 1A/1D$  adrenergic receptor antagonist, which reduces the tension of the smooth muscles of the prostate and urethra, allowing urine to pass more easily through the urethra and making urinating easier. In addition, it decreases the sense of urgency.

Tamsulosin Baldacci extended-release capsules are used in men for the treatment of lower urinary tract complaints associated with an enlarged prostate gland (benign prostatic hyperplasia). These complaints may include difficulty urinating (weak stream), dribbling, urgency and frequency of urination night and day.

2. What you need to know before you take Tamsulosin Baldacci 0.4 mg extended-release capsules

Do not take Tamsulosin Baldacci extended-release capsules if you are allergic (hypersensitive) to tamsulosin or any of the other ingredients of Tamsulosin Baldacci extended-release capsules. Hypersensitivity may present as a sudden, localised swelling

of the body's soft tissues (e.g. the throat or tongue), difficulty breathing and/or itching and rash (angioedema).

if you suffer from severe liver problems.

if you suffer from fainting due to a drop in blood pressure when you change your posture (when sitting or standing up).

#### Warnings and precautions

Periodic medical examinations are necessary to monitor the development of the condition for which you are being treated.

Rarely, fainting may occur while using Tamsulosin Baldacci extended-release capsules, as with other medicines of this type. At the first signs of dizziness or weakness, you should sit or lie down until the symptoms disappear.

If you suffer from severe kidney problems, tell your doctor.

If you are going to have or are scheduled to have an eye operation because your vision is blurred (cataracts) or increased pressure in the eye (glaucoma). Please tell your eye doctor if you have ever taken, take or plan to take Tamsulosin Baldacci extended-release capsules. The specialist can then take appropriate precautions regarding the medication and surgical techniques to be used. Ask your doctor if you should temporarily postpone or stop taking this medicine if you are going to have an eye operation because you have blurred vision (cataracts) or increased pressure in the eye (glaucoma).

#### Children and adolescents

Do not give this medicine to children or adolescents under the age of 18 years because the medicine has no effect in this population.

#### Other medicines and Tamsulosin Baldacci prolonged-release capsules

Taking Tamsulosin Baldacci extended-release capsules with other medicines in the same class ( $\alpha_1$  adrenergic receptor antagonists) may cause an unwanted decrease in blood pressure.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is very important to tell your doctor if you are being treated at the same time with other medicines that may decrease the elimination of Tamsulosin Baldacci in your body (e.g. ketoconazole, erythromycin).

#### Tamsulosin Baldacci extended-release capsules with food and beverages

You can take Tamsulosin Baldacci extended-release capsules with or without food.

#### Pregnancy, breastfeeding and fertility

Tamsulosin hydrochloride is not indicated for use in women.

Abnormal ejaculation has been reported in men (ejaculation problems). This means that semen does not leave the body through the urethra, but goes into the bladder (retrograde ejaculation) or that the volume of ejaculate is reduced or zero (ejaculatory insufficiency). This phenomenon is harmless.

#### Driving and using machines

There is no evidence that Tamsulosin Baldacci extended-release capsules impairs the ability to drive or use machinery or equipment. However, you should be aware that dizziness may occur and, in these cases, you should not take part in activities that require a lot of attention.

Tamsulosin Baldacci contains sodium.

This medicine contains less than 1 mmol (23 mg) sodium per capsule, i.e. it is virtually 'sodium-free'.

### 3. How to take Tamsulosin Baldacci 0.4 mg prolonged-release capsules

Take this medication exactly as directed by your doctor. Check with your doctor or pharmacist if you are not sure.

The usual dose is 1 capsule per day. You can take Tamsulosin Baldacci extended-release capsules with or without food, preferably at the same time of day.

The capsule should be swallowed whole and should not be crushed or chewed.

Tamsulosin Baldacci prolonged-release capsules are specially designed to gradually release the active substance as soon as it is ingested. Traces of the capsules can be seen in the faeces. Since the active substance has already been released, there is no risk of the capsules being less effective.

Usually, Tamsulosin Baldacci extended-release capsules are prescribed for a long period of time. The effects on bladder and urination are maintained during long-term treatment with Tamsulosin Baldacci extended-release capsules.

If you take more Tamsulosin Baldacci extended-release capsules than you should

Taking too much Tamsulosin Baldacci prolonged-release capsules can lead to an unwanted decrease in blood pressure and an increase in heart rate, accompanied by a feeling of faintness. Contact your doctor right away if you have taken more Tamsulosin Baldacci extended-release capsules than you should.

If you forget to take Tamsulosin Baldacci extended-release capsules

You can take your daily capsule later in the day if you forget to take it as recommended.

If you have not taken a day, you can continue to take your daily capsule as prescribed.

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

If you stop taking Tamsulosin Baldacci extended-release capsules

When treatment with Tamsulosin Baldacci extended-release capsule ends prematurely, your original complaints may come back. Therefore, take < Tamsulosin Baldacci extended-release capsules for as long as your doctor prescribes, even if your complaints have disappeared. Always consult your doctor if you consider discontinuing this therapy.

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

#### 4. Possible side effects

Like all medicines, Tamsulosin Baldacci extended-release capsule can cause side effects, although not everybody gets them.

Common (less than 1 in 10, more than 1 in 100 (1-10%)):

Dizziness, particularly when sitting or standing.

Abnormal ejaculation (ejaculation problems), this means that semen does not leave the body through the urethra, but goes into the bladder (retrograde ejaculation) or that the volume of ejaculation is reduced or null (ejaculatory insufficiency). This phenomenon is harmless.

Uncommon (more than 1 in 1,000 but less than 1 in 100 (0.1-1%)):

Headache, palpitations (the heart beats faster than normal and in a way that you can notice), a drop in blood pressure, e.g. when you get up quickly from sitting or lying down, sometimes in combination with dizziness, a runny or stuffy nose (rhinitis), diarrhoea, feeling sick and vomiting, constipation (constipation), weakness (asthenia), skin rashes, itching and itchy rash (hives).

Rare (more than 1 in 10,000 but less than 1 in 1,000 (0.01-0.1%)):

Fainting and sudden localized swelling in the soft tissues of the body (e.g. the throat or tongue), difficulty breathing and/or itching and rash, often as an allergic reaction (angioedema).

Very rare (less than 1 in 10,000 (<0.01%)):

Priapism (prolonged, unwanted, painful erection for which immediate medical treatment is required).

Rash, inflammation, and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages, or genitals (Stevens-Johnson syndrome).

Not known (cannot be estimated from the available data)

Blurred vision

Vision problems

- Nasal hemorrhage (epistaxis)

Severe skin rashes (erythema multiforme, exfoliative dermatitis)

Abnormal and irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), difficulty breathing (dyspnea).

If you are going to have eye surgery because your vision is blurred (cataracts) or increased pressure in the eye (glaucoma) and you are taking or have recently taken Tamsulosin Baldacci extended-release capsules, the pupil may dilate slightly and the iris (the circular coloured part of the eye) may become saggy during the procedure.

- Dry mouth (xerostomia)

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist or nurse. You can also report side effects directly to INFARMED, I.P. through the contacts below. By reporting side effects, you will be helping to provide more information about the safety of this medicine.

INFARMED, I.P.

Direção de Gestão do Risco de Medicamentos

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1749-004 Lisboa

Tel.: +351 21 798 71 403 73

Linha do Medicamento: 800222444 (gratuita)

Fax: + 351 21 798 73 97

Sítio da internet: <http://www.infarmed.pt/web/infarmed/submissaoram>

E-mail: [farmacovigilancia@infarmed.pt](mailto:farmacovigilancia@infarmed.pt)

#### 5. How to store Tamsulosin Baldacci 0.4 mg extended-release capsules

Store at a temperature below 30° C.

Store in the original packaging.

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

Do not use Tamsulosin Baldacci extended-release capsules after the expiry date which is stated on the blister and carton after 'EXP.:'. The expiry date corresponds to the last day of the month indicated.

Do not dispose of any medicines in the sewer or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

#### 6. Package contents and other information

What Tamsulosina Baldacci extended-release capsules contains

The active substance is tamsulosin hydrochloride 0.4 mg.

The other components are:

Pellet core: sodium alginate, methacrylic-ethylacrylate acid copolymer (1:1), glyceryl dibehenate, maltodextrin, sodium lauryl sulfate, polyethylene glycol 6000, polysorbate 80, sodium hydroxide, 30% dimethicone emulsion and colloidal anhydrous silica.

Capsule body: gelatin, purified water, red iron oxide (E172), titanium dioxide (E171) and yellow iron oxide (E172).

Capsule head: gelatin, purified water, red iron oxide (E172), titanium dioxide (E171) and yellow iron oxide (E172).

What Tamsulosin Baldacci prolonged-release capsules looks like and contents of the pack

Blister packs containing 10, 20, 30 or 60 extended-release capsules.  
Not all pack sizes may be marketed.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

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Manufacturer

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