

Product

TAMSULOSINE HYDROCHLORIDE YAMANOUCHI PHARMA 0.4 mg modified-release hard capsule

Company

(ASTELLAS PHARMA)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tamsulosine Hydrochloride Yamanouchi Pharma, 0.4 mg, modified-release hard capsule

Tamsulosine Hydrochloride

Read the entire package leaflet carefully before you start using this medicine.

- Keep this package leaflet. You may want to read it again later.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects listed affect you significantly or if you notice side effects not listed in this package leaflet, please inform your doctor or pharmacist.

This package leaflet contains:

1. What is Tamsulosine Hydrochloride Yamanouchi Pharma and what is it used for?
2. What do you need to know before taking Tamsulosine Hydrochloride Yamanouchi Pharma?
3. How to take Tamsulosine Hydrochloride Yamanouchi Pharma?
4. What side effects are possible?
5. How to store Tamsulosine Hydrochloride Yamanouchi Pharma?
6. Further information

1. What is Tamsulosin Hydrochloride Yamanouchi Pharma and what is it used for?

The active ingredient of Tamsulosin Hydrochloride Yamanouchi Pharma is Tamsulosin. It is an α 1A/1D-receptor blocker that reduces the muscle tone in the prostate and bladder neck. The bladder neck, which runs through the prostate, is thus less constricted, making urination easier. Additionally, the feeling of urgency to urinate decreases.

Tamsulosin Hydrochloride Yamanouchi Pharma is used in men to treat lower urinary tract symptoms associated with benign prostatic hyperplasia. The symptoms include difficulties in urination, frequent urination (including at night), urgency even after urination, and dribbling.

2. What should you consider before taking Tamsulosin Hydrochloride Yamanouchi Pharma?

Tamsulosin Hydrochloride Yamanouchi Pharma must not be taken

if you are allergic (hypersensitive) to Tamsulosin Hydrochloride or any of the other ingredients of the product. Hypersensitivity is manifested by sudden swelling of soft tissues (e.g., throat or tongue), difficulty breathing, and/or itching and rash (angioedema).

if you suffer from severe liver insufficiency (insufficient liver function)

if you have had problems with dizziness due to blood pressure drop when sitting up or standing up in the past

Special caution is required when taking Tamsulosin Hydrochloride Yamanouchi Pharma. Regular medical check-ups are necessary to assess the progression of your condition. In rare cases, taking Tamsulosin Hydrochloride Yamanouchi Pharma can cause fainting when sitting up or standing up. If you feel dizzy or weak, you should lie down or sit down until it passes.

If you have severe kidney problems, you should inform your doctor.

If you need to undergo eye surgery for lens clouding (cataract) or increased intraocular pressure (glaucoma), please inform your ophthalmologist that you have taken, are taking, or plan to take Tamsulosin Hydrochloride Yamanouchi Pharma. The ophthalmologist can then take appropriate precautions with medications and surgical procedures. Ask your doctor if you should postpone or temporarily stop taking this medication if you are undergoing eye surgery for lens clouding or increased intraocular pressure (glaucoma).

Children

Do not administer this medication to children or adolescents under 18 years of age, as it is not effective in this

population.

Taking Tamsulosin Hydrochloride Yamanouchi Pharma with other medications. Simultaneous administration of other drugs with the same mechanism of action as Tamsulosin Hydrochloride Yamanouchi Pharma (alpha-1 adrenoceptor blockers) can lead to an undesirable drop in blood pressure.

It is particularly important to inform your doctor if you are being treated simultaneously with drugs that can reduce the excretion of Tamsulosin Hydrochloride Yamanouchi Pharma (e.g., ketoconazole, erythromycin).

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including those not prescribed.

When taking Tamsulosin Hydrochloride Yamanouchi Pharma with food and drink. Tamsulosin Hydrochloride Yamanouchi Pharma should be taken after breakfast or after the first meal of the day.

Pregnancy, breastfeeding, and fertility

Tamsulosin Hydrochloride Yamanouchi Pharma is not intended for use in women.

In men, ejaculation disorders have been reported. This means that the semen does not leave the body through the urethra but instead flows into the bladder (retrograde ejaculation) or the volume of semen is reduced or absent (absent ejaculation). This phenomenon is harmless.

Driving and using machines

The effects on the ability to drive and use machines have not been studied. However, it must be considered that dizziness may occur. In this case, you should not perform activities that require attention.

3. How to take Tamsulosine Hydrochloride Yamanouchi Pharma?

Always take the medicine exactly as instructed, unless your doctor has prescribed otherwise. If in doubt, consult your doctor or pharmacist.

The usual dosage is 1 capsule per day. The capsule should be taken after breakfast or after the first meal of the day. Swallow the capsule whole with some water. Do not bite or chew the capsule. Tamsulosine Hydrochloride Yamanouchi Pharma is usually prescribed for a longer period. The effects on the bladder and urination are maintained during long-term treatment with Tamsulosine Hydrochloride Yamanouchi Pharma.

If you have taken more Tamsulosine Hydrochloride Yamanouchi Pharma than you should: Taking too much can lead to an undesirable drop in blood pressure and a rapid heartbeat, making you feel faint.

In case of an overdose of Tamsulosine Hydrochloride Yamanouchi Pharma, please contact your doctor or pharmacist immediately or call the poison control center (070/245.245).

If you forget to take Tamsulosine Hydrochloride Yamanouchi Pharma:

If you forget a capsule after breakfast or the first meal of the day, you should still take the capsule. If you notice this the next day, you do not need to take the missed capsule. Never take a double dose of Tamsulosine Hydrochloride Yamanouchi Pharma to make up for a missed dose.

If you stop taking Tamsulosine Hydrochloride Yamanouchi Pharma

If treatment with Tamsulosin Hydrochloride Yamanouchi Pharma is stopped prematurely, the original symptoms may return. Therefore, take Tamsulosin Hydrochloride Yamanouchi Pharma as long as your doctor prescribes it, even if your symptoms have already subsided. Consult your doctor if you wish to stop the treatment.

If further information about the medication is desired, contact your doctor or pharmacist.

4. What side effects are possible?

Like all medicines, Tamsulosin Hydrochloride Yamanouchi Pharma can have side effects, but they do not occur in everyone.

Common (in less than 1 in 10, but more than 1 in 100 patients (1-10%)): Dizziness, especially when sitting up or standing up.

Ejaculation disorders; this means that the semen does not leave the body through the urethra but instead enters the bladder (retrograde ejaculation) or the volume of semen is reduced or absent (absent ejaculation). This phenomenon is harmless.

Sometimes (in more than 0.1%, but less than 1% of patients) occur: Headaches, palpitations, drop in blood pressure due to rapid standing up from a sitting or lying position, sometimes accompanied by dizziness (orthostatic hypotension), stuffy nose (rhinitis), diarrhea, nausea, vomiting, constipation (obstipation), feeling of weakness (asthenia), rash, itching, and hives (urticaria).

Rarely (in more than 0.01%, but less than 0.1% of patients) occur: Fainting (syncope) and sudden fluid accumulation in the skin and mucous membranes (e.g., angioedema).

Very rarely (in less than 0.01% of patients), priapism occurs. This is a prolonged, painful, unwanted erection that must be treated by a doctor.

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

unknown (frequency cannot be estimated from the available data):

Blurred vision,
Visual disturbances,
Nosebleeds (epistaxis),

- Severe skin rashes (erythema multiforme, exfoliative dermatitis). Abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), breathing difficulties (dyspnea). If you are undergoing eye surgery for lens clouding (cataract) or increased eye pressure (glaucoma), and are already taking or have recently taken Tamsulosin Hydrochloride Yamanouchi Pharma, the pupil may dilate poorly and the iris (the colored part of the eye) may become flaccid during the procedure.
- Dry mouth

Please inform your doctor or pharmacist if any of the listed side effects significantly affect you or if you notice side effects not listed in this leaflet.

Reporting suspected side effects

If you notice side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this package leaflet. You can also report side effects directly via the national reporting system.

Belgium

Federal Agency for Medicines and Health Products
Vigilance Department, Eurostation II, Victor Hortaplein, 40/40
B-1060 Brussels
website : www.fagg-afmps.be
e-mail: patientinfo@fagg-afmps.be

Luxembourg

Directorate of Health
Division of Pharmacy and Medicines
Villa Louvigny – Allée Marconi
L-2120 Luxembourg
website : <http://www.ms.public.lu/fr/activites/pharmacie-medicament/index.html>

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Tamsulosine Hydrochloride Yamanouchi Pharma?

Store in the original package

Keep medicines out of the reach of children.

Do not use Tamsulosine Hydrochloride Yamanouchi Pharma after the expiry date stated on the carton after EXP.

The medicine must not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of the medicine when you no longer need it. This measure helps protect the environment.

6. Further information

What Tamsulosine Hydrochloride Yamanouchi Pharma contains

The active substance is Tamsulosin Hydrochloride 0.4 mg

The other ingredients are:

Capsule content: microcrystalline cellulose E460 – methacrylic acid – ethyl acrylate copolymer (1:1) – polysorbate (80) E433 - sodium lauryl sulfate - triacetin E1518 - calcium stearate E470a - talc E553b

Capsule shell: gelatin - indigotine E132 - titanium dioxide E171 – yellow and red iron oxide E172

Printing ink: shellac E904 - propylene glycol E1520 - black iron oxide E172

Tamsulosine Hydrochloride Yamanouchi Pharma contains neither gluten nor sugar.

What Tamsulosine Hydrochloride Yamanouchi Pharma looks like and contents of the pack

Tamsulosine Hydrochloride Yamanouchi Pharma, capsules are orange/olive green with the imprint '0.4' and '701'. The capsules are packed in aluminum blister packs in a carton box.

The packs contain 10, 20, 30, 50, 60, 90, 100, or 200 tablets.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Astellas Pharma Europe B.V.

Sylviusweg 62

2333 BE Leiden

Netherlands

Manufacturer

Astellas Pharma Europe B.V.

Sylviusweg 62

2333 BE Leiden

Netherlands

Approval number

PP/Alu : BE278713

Sales restriction

Prescription only.

This package leaflet was last revised in: 12/2013

This package leaflet was last approved on: 18.03.2014

Price

Name	Packaging	CNK	Price	RV	Type
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TAMSULOSINE HYDROCHLORIDE YAMANOUCI PHARMA	30 CAPS 0,4MG	2274- €	D 496	Generic 23.00
TAMSULOSINE HYDROCHLORIDE YAMANOUCI PHARMA	90 CAPS 0,4MG	2274- €	D 488	Generic 49.50
TAMSULOSINE HYDROCHLORIDE YAMANOUCI PHARMA	200 CAPS 0.4MG	2495- € 810	D 83.75	Generic

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