

## Package leaflet: Information for the patient

### Tamsulosin hydrochloride SUN Pharma 400 micrograms prolonged-release hard capsules tamsulosin hydrochloride

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

#### 1. What Tamsulosin capsules is and what it is used for

Tamsulosin hydrochloride SUN Pharma 400 micrograms prolonged-release hard capsules (called tamsulosin capsules throughout this leaflet) contains the active ingredient tamsulosin. This is a selective  $\alpha_{1A/1D}$ -adrenoceptor antagonist. 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 capsules is used in men for the treatment of the complaints of the lower urinary tract associated with an enlarged prostatic gland (benign prostatic hyperplasia) These complaints may include difficulty urinating (poor stream), dribbling, urgency and having to urinate frequently at night as well as during the day.

#### 2. What you need to know before you take tamsulosin capsules

##### **Do not take tamsulosin capsules:**

- if you are allergic to tamsulosin hydrochloride or any of the other ingredients of this medicine (listed in section 6). Hypersensitivity may present as sudden local swelling of the soft tissues of the body (e.g. the throat or tongue), difficult breathing and/or itching and rash (angioedema).
- if you suffer from severe liver problems.
- if you suffer from fainting due to reduced blood pressure when changing posture (going to sit or stand up) or you feel dizzy.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking tamsulosin capsules .

- Periodic medical examinations are necessary to monitor the development of the condition you are being treated for.
- Before starting treatment you should tell your doctor if you are suffering from any other disease.
- Rarely, fainting can occur during the use of tamsulosin capsules as with other medicinal products of this type.  
At the first signs of dizziness or weakness you should sit or lie down until they have disappeared.
- if you suffer from severe kidney or liver problems, tell your doctor.
- 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 capsules can may cause complications (intraoperative Floppy Iris Syndrome [IFIS]) during the surgery. The specialist can then take appropriate precautions with respect to medication and surgical techniques to be used. Ask your doctor whether or not you should postpone or temporarily stop taking this medicine when undergoing a cataract- or glaucoma surgery because of a cloudy lens.

### **Children and adolescents**

Do not give this medicine to children or adolescent under 18 years because it does not work in this population.

### **Other medicines and tamsulosin capsules**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular tell your doctor or pharmacist if you are taking:

- Diclofenac (an anti-inflammatory painkiller) and warfarin (used to prevent blood clotting).
- Medicines to potentially influencing the blood level of tamsulosin such as verapamil or diltiazem (used to lower your blood pressure), ritonavir and indinavir (used to treat HIV infection), ketoconazole, itraconazole or erythromycin (used to treat fungal or bacterial infection).

Taking Tamsulosin capsules together with other medicines from the same class ( $\alpha_1$ -adrenoceptor antagonists such as doxazosin, indoramin, prazosin or alfuzosin) may cause an unwanted decrease in blood pressure.

It is especially important to inform your doctor if you are being treated at the same time with medicines that may decrease the removal of tamsulosin capsules from the body (for example, ketoconazole, erythromycin).

You should only take medicine concomitantly with tamsulosin capsules if your doctor allows it.

### **Tamsulosin capsules with food, drink and alcohol**

Tamsulosin capsules must be taken after breakfast or the first meal of the day.

**Pregnancy, breast-feeding and fertility**

This section is not relevant, because tamsulosin capsules is not indicated for use in women.

Impaired sexual functions in males have been reported with tamsulosin capsules.

**Driving and using machines**

There is no evidence that tamsulosin capsules affects the ability to drive or to operate machinery or equipment.

However, you should bear in mind that dizziness can occur, in which case you should not undertake activities that require attentiveness.

**Tamsulosin capsules contains orange yellow S, azorubine and ponceau 4R**

Allergic reactions may occur due to the presence of colouring agents used in this product: orange yellow S (E110), azorubine (E122) and ponceau 4R (E124).

**Tamsulosin capsules contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per capsule, hard, that is to say essentially 'sodium-free'.

**3. How to take tamsulosin capsules**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The dosage is one capsule per day to be taken after breakfast or the first meal of each day. The capsule should be taken while standing or sitting (not lying down) with a glass of water. The capsule is to be swallowed whole and must not be crushed or chewed, as this would impair the delayed release of the active ingredient. Usually, tamsulosin capsules is prescribed for long periods of time. The effects on the bladder and on urination are maintained during long-term treatment with tamsulosin capsules.

**If you take more Tamsulosin capsules than you should**

Taking too many capsules of tamsulosin capsules may lead to an unwanted decrease in blood pressure and an increase in heart rate, with feelings of faintness. Contact your doctor immediately if you have taken too much tamsulosin capsules.

**If you forget to take tamsulosin capsules**

You may take your daily tamsulosin capsules later the same day if you have forgotten to take it as recommended. If you have missed a day, just 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 capsules**

When treatment with tamsulosin capsules is stopped prematurely, your original complaints may return. Therefore use tamsulosin capsules as long as your doctor prescribes, even if your complaints have disappeared already. Always consult your doctor, if you consider stopping 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, this medicine can cause side effects, although not everybody gets them.

**Serious side effects are rare or very rare. Stop taking this medicine and see a doctor straight away if you experience any of the following symptoms - you may need medical treatment:**

- Sudden local swelling of soft tissues (e.g., throat or tongue), difficulty breathing, and/or itching and skin rash, often in the form of an **allergic reaction** (angioedema) (may affect up to 1 in 1,000 people)
- priapism (painful, persistent, involuntary erection of the penis), in which case immediate medical aid is needed (may affect up to 1 in 10,000 people)
- a severe inflammatory eruption of the skin and mucous membranes, which is an allergic reaction to drugs or other substances called Stevens-Johnson syndrome, (may affect up to 1 in 10,000 people)
- serious skin rashes (erythema multiforme, dermatitis exfoliative) (frequency cannot be estimated from the available data).

The following side effects have also been reported:

Common (may affect up to 1 in 10 people):

- Dizziness, particularly when going to sit or stand up.
- Ejaculation disorders
- Retrograde ejaculation; this means that semen does not leave the body via the urethra, but instead goes into the bladder. This phenomenon is harmless.
- Ejaculation failure.

Uncommon (may affect up to 1 in 100 people):

- Headache
- palpitations (the heart beats more rapidly than normal and it is also noticeable)
- reduced blood pressure e.g. when getting up quickly from a seating or lying position sometimes
- associated with dizziness
- runny or blocked nose (rhinitis)
- diarrhoea, feeling sick and vomiting
- constipation, weakness (asthenia), rashes, itching and hives (urticaria).

Rare (may affect up to 1 in 1000 people):

- fainting
- weakness

Not known (frequency cannot be estimated based on available data)

- Vision blurred, visual impairment
- Nose bleed
- Dry mouth
- Abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), difficult breathing (dyspnoea).
- If you are undergoing eye surgery because of cloudiness of the lens (cataract) and are already taking or have previously taken tamsulosin capsules, the pupil may dilate poorly

and the iris (the coloured circular part of the eye) may become floppy during the procedure.

If you have to undergo eye surgery due to a clouding of the lens (cataract) or increased intraocular pressure (glaucoma) and are taking or have recently taken tamsulosin capsules, insufficient dilation of the pupil and drooping of the iris (the colored circular part of the eye) may occur during surgery.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

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

## **5. How to store Tamsulosin capsules**

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

This medicinal product does not require any special storage conditions

Do not use this medicine after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month.

Never dispose of medicines in the wastewater (e.g. not in the toilet or sink). Ask your pharmacy how to dispose of the medicine when you are no longer using it. By doing so, you will help protect the environment.

## **6. Contents of the pack and other information**

### **What Tamsulosin capsules contains**

The active substance is tamsulosin hydrochloride. One prolonged release capsule contains 400 micrograms of tamsulosin hydrochloride.

**The other ingredients are:** capsule contents: cellulose microcrystalline PH101, magnesium stearate, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion, sodium hydroxide, triacetin, titanium dioxide (E171), purified talc.

Capsule body: gelatine, orange yellow S (E110), ponceau 4R (E124), quinoline yellow (E104), brilliant blue (E133), titanium dioxide (E171).

Cap composition: gelatine, yellow iron oxide (E172), brilliant blue (E133), azorubine (E122), titanium dioxide (E171).

Printing ink: shellac, black iron oxide (E172), potassium hydroxide.

### **What Tamsulosin capsules looks like and contents of the pack**

Tamsulosin capsules comprise of light Brown cap/Orange body of size '2' imprinted with 'R' on cap and 'TSN400' on body in black edible ink containing white to off-white granules.  
Packs of 1, 2, 4, 7, 10, 14, 20, 28, 30, 50, 56, 60, 90, 98,100 or 200 prolonged release capsules.

Not all pack sizes may be marketed.

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