

## PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

### **Tamnic 400 micrograms modified-release capsules, hard** 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 Tamnic 400 micrograms is and what it is used for
2. What you need to know before you take Tamnic 400 micrograms
3. How to take Tamnic 400 micrograms
4. Possible side effects
5. How to store Tamnic 400 micrograms
6. Contents of the pack and other information

#### **1. What Tamnic 400 micrograms is and what it is used for**

Tamsulosin is an  $\alpha_{1A}$ -adrenoreceptor blocker. It relaxes the muscles in the prostate and urinary tract.

Tamsulosin is prescribed to alleviate urinary symptoms caused by an enlarged prostate (benign prostatic hyperplasia). By relaxing the muscle it enables a more easily pass of urine and helps urination.

#### **2. What you need to know before you take Tamnic 400 micrograms**

##### **DO NOT take Tamnic 400 micrograms if you:**

- Are allergic to tamsulosin or any of the other ingredients of this medicine listed in section 6 [symptoms may include: swelling of your face and throat (angioedema)].
- Have a history of a fall in blood pressure on standing up, which causes dizziness, light-headedness or fainting.
- Have severe liver problems.

#### **Warnings and precautions:**

Talk to your doctor or pharmacist before taking Tamnic 400 micrograms:

- Experience dizziness or light-headedness, especially after standing up. Tamnic 400 micrograms may lower your blood pressure, causing these symptoms. You should sit or lie down until the symptoms have gone.
- Suffer from severe kidney problems. The normal dose of Tamnic 400 micrograms may not have the expected effect when your kidneys are not functioning normally.
- Experience swelling in your face or throat. These are symptoms of angioedema (see section 2, DO NOT take Tamnic 400 micrograms). You must stop taking tamsulosin immediately and contact your doctor. You should not be restarted on tamsulosin.
- Are planning to undergo eye surgery for cataract (vision loss, especially for blue colours) or glaucoma (increased pressure in the eye). A condition called *Intraoperative Floppy Iris Syndrome* (IFIS) can occur during surgery if you are taking, or recently have taken, tamsulosin. IFIS can cause complications during surgery. It is recommended you stop taking tamsulosin 1-2 weeks before surgery. Contact your doctor and your surgeon before to discuss your situation.

### Children

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

### **Other medicines and Tamnic 400 micrograms**

Other medicines may be affected by tamsulosin. They, in turn, may affect how well tamsulosin works. Tamsulosin can interact with:

- Diclofenac, a pain killer and anti-inflammatory medicine. This medicine can speed up the removal of tamsulosin from your body, thereby shortening the time tamsulosin is effective.
- Warfarin, a medicine to prevent blood clotting. This medicine can speed up the removal of tamsulosin from your body, thereby shortening the time tamsulosin is effective.
- Medicines to lower your blood pressure such as verapamil and diltiazem.
- Medicines to treat HIV such as ritonavir or indinavir.
- Medicines to treat a fungal infection such as ketoconazole or itraconazole.
- Another  $\alpha_{1A}$ -adrenoreceptor blocker such as doxazosin, indoramin, prazosin or alfuzosin. The combination may lower your blood pressure, causing dizziness or light-headedness.
- Erythromycin, an antibiotic used to treat infections.

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

### **Tamnic 400 micrograms with food and drink**

You should take tamsulosin with a glass of water after breakfast or after your first meal of the day.

### **Pregnancy, breast-feeding and fertility**

Tamsulosin hydrochloride 0.4 mg 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**

There is no information on the effects of tamsulosin on the ability to drive and use machines. You should take into account that tamsulosin may cause dizziness and light-headedness. Only drive or use machines if you feel alright.

### **Tamnic 400 micrograms contains sodium**

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

### **3. How to take Tamnic 400 micrograms**

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

The recommended dose is one capsule per day taken after breakfast or after your first meal of the day.

Swallow the capsule whole with a glass of water, while standing or sitting (not while lying down). It is important that you do not break or crush the capsule as this may influence how well Tamnic 400 micrograms works.

### **If you take more Tamnic 400 micrograms than you should**

Your blood pressure may suddenly drop if you take more Tamnic 400 micrograms than you should. You may experience dizziness, weakness and fainting. Lie down to minimise the effects of low blood pressure and then contact your doctor. Your doctor may give you medicines to restore your blood pressure and monitor your body function. When necessary your doctor may empty your stomach and

give you a laxative to remove any tamsulosin not yet taken up in the blood from your body.

**If you forget to take Tamnic 400 micrograms**

Do not take a double dose to make up for a forgotten dose. Just take the next dose at the usual time. 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.

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

- Dizziness
- 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.

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

- Headache
- Feeling your heartbeat (palpitations)
- A fall in blood pressure on standing up, which causes dizziness, light-headedness or fainting (orthostatic hypotension)
- Swelling and irritation inside the nose (rhinitis)
- Constipation
- Diarrhoea
- Feeling sick (nausea)
- Vomiting
- Rash
- Itching
- Hives (urticaria)
- Feeling of weakness (asthenia)

**Rare (may affect up to 1 in 1,000 people):**

Fainting (syncope)

- Serious allergic reaction which causes swelling of the face or throat (angio-oedema): Contact your doctor immediately, you should not be restarted on tamsulosin (see Section 2, DO NOT take Tamnic 400 micrograms)

**Very rare (may affect up to 1 in 10,000 people):**

- Painful erection (priapism)
- Serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome)

**Not known (frequency cannot be estimated from the available data):**

- Serious skin rashes (erythema multiforme, dermatitis exfoliative)
- Nose bleeds (epistaxis)
- Blurred vision or impaired vision
- During cataract or glaucoma surgery a small pupil situation, known as Intraoperative Floppy Iris Syndrome (IFIS), has been associated with therapy of tamsulosin during post-marketing surveillance (See also Section 2, Warnings and precautions)
- Dry mouth

Additional side effects (post-marketing experience):

In addition to the side effects listed above, abnormal heart rhythm (atrial fibrillation), irregular heart beat (arrhythmia), faster heart beat (tachycardia) and shortness of breath (dyspnoea) have been reported in association with tamsulosin use.

### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Tamnic 400 micrograms**

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

Do not use this medicine after the expiry date which is stated on the packaging after 'EXP'. The first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that month.

Store the blisters in the original package in order to protect from moisture.

Keep the container tightly closed in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

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

#### **What Tamnic 400 micrograms contains**

- The active substance is tamsulosin hydrochloride 400 micrograms.

The other ingredients are:

Capsule: Microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer, polysorbate 80, sodium laurilsulfate, triethyl citrate, talc.

Capsule body: Gelatin, indigotine (E132), titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172).

#### **What Tamnic 400 micrograms looks like and contents of the pack**

Orange/olive-green modified-release capsule. The capsules contain white to off-white pellets.

They are supplied in blister packs with 10, 14, 15, 20, 28, 30, 48, 50, 56, 60, 90, 98, 100 or 200 modified-release capsules or containers with 60 or 250 modified-release capsules.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Lamp San Prospero S.p.A., Via della Pace, 25/A, 41030 San Prospero (Modena), Italy

#### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria:	Tamsulosin Stada retard 0,4 mg – Kapseln
Belgium:	Tamsulosine EG 0,4 mg capsules met gereguleerde afgifte, hard
Denmark:	Omnistad
Estonia:	Tamsulosin STADA
Germany:	Tamsulosin STADA 0,4 mg Hartkapseln mit veränderter Wirkstofffreisetzung
Hungary:	Urostat 0,4 mg módosított hatóanyagleadású kémeny kapszula

Ireland:	Tamnic 400 micrograms modified-release capsule, hard
Italy:	Tamsulosina EG 0,4 mg capsule rigide a rilascio modificato
Latvia:	Tamsulosin STADA 0,4 mg ilgstošās darbības cietās kapsulas
Lithuania:	Tamsulosin STADA 0,4 mg modifikuoto atpalaidavimo kietos kapsulės
Luxembourg:	Tamsulosine EG 0,4 mg gélules à libération modifiée
The Netherlands:	Tamsulosine HCI CF 0,4 mg, capsules met gereguleerde afgifte
Spain:	Tamsulosina STADA 0,4 mg cápsulas duras de liberación modificada EFG
United Kingdom:	Tabphyn MR Capsules 400 micrograms

**This leaflet was last revised in July 2024.**