

**PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**  
**Tabphyn™ MR 400 microgram 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 Tabphyn™ MR 400 microgram Capsules are and what they are used for
2. What you need to know before you take Tabphyn™ MR 400 microgram Capsules
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### 1. What Tabphyn™ MR 400 microgram Capsules are and what they are used for

Tamsulosin is an  $\alpha_1$  adrenoceptor 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 urine to be passed more easily and helps urination.

### 2. What you need to know before you take Tabphyn™ MR 400 microgram Capsules

#### DO NOT take Tabphyn™ MR 400 microgram Capsules 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 (angio-edema)]
- have a history of a fall in blood pressure on standing up, which causes dizziness, light-headedness or fainting
- have severe liver problems.

#### Tabphyn™ MR 400 microgram Capsules warnings and precautions

Talk to your doctor or pharmacist before taking Tabphyn™ MR 400 microgram Capsules if you:

- experience dizziness or light-headedness, especially after standing up. Tabphyn™ MR 400 microgram Capsules 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 Tabphyn™ MR 400 microgram Capsules may not have the expected effect when your kidneys are not functioning normally
- experience swelling in your face or throat. These are symptoms of angio-edema (see section 2, DO NOT take Tabphyn™ MR 400 microgram Capsules). 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). A condition called Intraoperative Floppy Iris Syndrome (IFIS) can occur during surgery if you are taking, or have recently 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 Tabphyn™ MR 400 microgram Capsules

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  $\alpha_1$  adrenoceptor 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.

#### Tabphyn™ MR 400 microgram Capsules with food and drink

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

#### 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 well.

#### Tabphyn™ MR 400 microgram Capsules

##### 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 Tabphyn™ MR 400 microgram Capsules

Always take this medicine exactly as your doctor has told you to. 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 Tabphyn™ MR 400 microgram Capsules work.

#### If you take more Tabphyn™ MR 400 microgram Capsules than you should

Your blood pressure may suddenly drop if you take more Tabphyn™ MR 400 microgram Capsules 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 Tabphyn™ MR 400 microgram Capsules

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-edema): Contact your doctor immediately, you should not be restarted on tamsulosin (see Section 2, DO NOT take Tabphyn™ MR 400 microgram Capsules).

### 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 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, Tabphyn™ MR 400 microgram Capsules 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 heartbeat (arrhythmia), faster heartbeat (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, 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 website:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for 'MHRA Yellow Card' in the Google Play or Apple App Store

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

## 5. How to store Tabphyn™ MR 400 microgram Capsules

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 protect the environment.

## 6. Contents of the pack and other information

### What Tabphyn™ MR 400 microgram Capsules contain

- The active substance is Tamsulosin hydrochloride 400 microgram.
- 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 Tabphyn™ MR 400 microgram Capsules look like and contents of the pack

Orange/olive-green modified-release capsules. 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:

Genus Pharmaceuticals  
Linthwaite, Huddersfield, HD7 5QH, UK.

### Manufacturer:

Genus Pharmaceuticals  
Linthwaite, Huddersfield, HD7 5QH, UK.  
STADA Arzneimittel AG  
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**POM**

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Tabphyn™ MR 400 microgram Capsules

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