

# DIFFUNDOX XL 400 MICROGRAM 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 Diffundox XL is and what it is used for
2. What you need to know before you take Diffundox XL
3. How to take Diffundox XL
4. Possible side effects
5. How to store Diffundox XL
6. Contents of the pack and other information

### 1. WHAT DIFFUNDOX XL IS AND WHAT IT IS USED FOR

The name of this medicine is Diffundox XL 400 microgram modified-release Capsules (referred to as Diffundox XL throughout this leaflet). The active ingredient in Diffundox XL is 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.

Diffundox XL modified-release capsules are 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 DIFFUNDOX XL

#### Do not take Diffundox XL 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**, difficult breathing and/or itching and rash (angio-oedema)).
- 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 Diffundox XL if you

- experience **dizziness or light-headedness**, especially after standing up. Tamsulosin 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 tamsulosin may not have the expected effect when your kidneys are not functioning normally.
- experience **swelling in your face or throat**, difficult breathing and/or itching and rash. These are symptoms of angio-oedema (see section 2, Do not take Diffundox XL). You should stop taking tamsulosin immediately and contact your doctor. You should not be restarted on tamsulosin.
- are undergoing or have been scheduled for eye surgery because of cloudiness of the lens (cataract). An eye condition called Intraoperative Floppy Iris Syndrome may occur (see section 4), please inform your eye specialist that you have previously used, are using, or are planning to use tamsulosin. 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 eye surgery because of a cloudy lens.

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

#### 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 Diffundox XL

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

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.
- **another  $\alpha$ 1A-adrenoceptor blocker**. The combination may lower your blood pressure, causing dizziness or light-headedness.
- medicines that may decrease the removal of Diffundox XL from the body (for example, ketoconazole, erythromycin).

#### Diffundox XL with food, drink and alcohol

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

#### Pregnancy, lactation and fertility

##### Pregnancy and lactation

Diffundox XL is not indicated for use in women therefore information on pregnancy and lactation is not relevant.

##### Fertility

Difficulties with ejaculation have been reported in association with tamsulosin use (see section 4).

#### 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.

### 3. HOW TO TAKE DIFFUNDOX XL

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

The **usual 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 tamsulosin works.

##### Patients with impaired hepatic or renal function

In patients with renal or mild to moderate hepatic insufficiency it is not necessary to adjust the dose.

##### Use in children and adolescents

These capsules are not intended for use in children and adolescents.

#### If you take more Diffundox XL than you should

Your blood pressure may suddenly drop if you take more tamsulosin 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 Diffundox XL**

You may take your daily Diffundox XL 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. Never take a double dose to make up for the forgotten capsule.

**If you stop taking Diffundox XL**

When treatment with Diffundox XL is stopped prematurely, your original complaints may return. Therefore use Diffundox XL 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.

**Stop taking Diffundox XL and seek medical help immediately if you get:**

- hypersensitivity reaction with purplish spots or patches on the skin, blisters on the skin, peeling of the skin, (high fever, joint pain and / or eye inflammation (Stevens-Johnson syndrome)\*
- serious allergic reaction which causes swelling of the face or throat (angio-oedema)\*\*

The side effects which may occur are listed below in groups according to the frequency:

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

- Dizziness.

**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).
- Angio-oedema\*\*.

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

- Painful, prolonged, unwanted erection for which immediate medical treatment is required (priapism).
- Stevens-Johnson syndrome\*.

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

- Disturbances of vision, blurred vision.
- Bleeding from the nose (epistaxis).
- Rash with red irregular spots (erythema multiforme).
- Erythema and scaling of the skin (dermatitis exfoliative).
- Difficulties with ejaculation, little or no semen ejaculated at sexual climax, cloudy urine following sexual climax.
- Abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia).
- Difficult breathing (dyspnoea).
- Dry mouth.

During eye surgery a condition called Floppy Iris Syndrome (IFIS) may occur: the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during surgery. For more information see section 2, Warnings and precautions.

**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 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 DIFFUNDOX XL**

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 expiry date refers to the last day of that month.

Store the blisters in the original package. Keep the container tightly closed.

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 Diffundox XL contains**

The active substance is tamsulosin hydrochloride 0.4 mg.

The other ingredients are:

Capsule content: 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 Diffundox XL looks like and contents of the pack**

Diffundox XL 400 microgram Capsules is a hard gelatin modified-release capsule with orange coloured body and olive coloured cap.

The capsule is filled with white to off-white pellets.

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

Not all pack sizes may be marketed.

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

Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

**Manufacturer(s)**

Synthon BV, Microweg 22, 6545 CM Nijmegen, Netherlands or Synthon Hispania S.L.,

Castelló, Polígono las Salinas, 08830 Sant Boi de Llobregat, Spain or Quinta-Analytica s.r.o, Pražská 1486/18c, 102 00 Prague 10, Czech Republic.

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