

## **FLOEZY**

Tamsulosin hydrochloride prolonged released tablets (0.4mg)

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

### **WHAT IS IN THIS LEAFLET**

- a) What FLOEZY is and what it is used for
- b) Before you use FLOEZY
- c) How to take FLOEZY
- d) Possible Side effects
- e) How to store FLOEZY
- f) Further information

#### **a) WHAT FLOEZY IS AND WHAT IT IS USED FOR**

##### **What is FLOEZY**

FLOEZY is a prolonged release tablet which contains a medicine called tamsulosin. This belongs to a group of medicines called 'alpha blockers' (or alpha1A-adrenoceptor antagonists).

It acts by relaxing the muscles in the prostate and urethra (the tube that carries urine to the outside), and lets urine pass more readily through the urethra and aids urination. In the prostate gland, bladder and urethra there are specialized cells containing alpha1A-receptors that cause the muscles in the urethra to tighten. FLOEZY is an alpha1A-adrenoceptor blocker, which reduces the action of these

specialised cells and relaxes the muscles making it easier to pass water.

##### **What FLOEZY is used for**

FLOEZY is used to treat the symptoms associated with benign prostatic hyperplasia (BPH) which is enlargement of the prostate gland. These symptoms include difficulty in starting to pass water, frequent trips to the toilet to pass water, a feeling of not completely emptying the bladder and having to get up several times in the night to pass water.

##### **b) Before you use FLOEZY**

###### **Do not use FLOEZY**

If you;

- are allergic to tamsulosin or any of the other ingredients of FLOEZY.
- have a severe liver condition
- have ever fainted or felt dizzy when suddenly sitting or standing up.

Dizziness can sometimes occur when taking FLOEZY, particularly if you are also taking other alpha1- blockers. If you do feel weak or dizzy make sure you sit or lie down straight away until the symptoms have disappeared.

###### **Take special care with FLOEZY**

Talk to your doctor before using FLOEZY

- If you have kidney problems
- 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 hydrochloride. 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 (cataract) or increased pressure in the eye (glaucoma).

### **Taking with other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because FLOEZY can affect the way that some other medicines work and some other medicines can affect the way that FLOEZY works.

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

- 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
- Other alpha blockers such as doxazosin, indoramin, prazosin or alfuzosin
- Erythromycin, an antibiotic used to treat infections

Please inform your doctor that you are on FLOEZY before any operation or dental procedure as there is a potential that your medicine may interfere with the effects of the anaesthetic.

### **Taking FLOEZY with food and drink**

It can be taken with or without food.

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

FLOEZY 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 available on whether FLOEZY affects the ability to drive or to operate machinery or

equipment. However, it is known that FLOEZY may cause drowsiness, blurred vision, dizziness and fainting. If you suffer from these do not drive or operate machinery.

### **c) How to take FLOEZY**

Always take FLOEZY exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The recommended dose for adults and the elderly is one tablet each day.

It can be taken with or without food. Swallow the tablet whole. Do not crunch or chew.

Your doctor may want to examine you from time to time whilst you are taking this medicine.

### **Use in children**

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

### **If you take more FLOEZY than you should**

If you have taken too many tablets, contact your doctor immediately or go to the nearest hospital casualty department taking any remaining medication and this patient information leaflet with you.

### **If you forget to take FLOEZY**

You may take your tablet later the same day if you have forgotten to take it earlier. If you have missed a day, just continue to take your daily tablet from the next day. Do not take a double dose to make up for a missed dose.

### **If you stop taking FLOEZY**

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

**d) Possible Side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and consult your doctor immediately if any of the following occur – you may need medical treatment.

**Rare (affects less than 1 in 1000 people)**

- Swelling of the face, throat or tongue with breathing problems linked to allergy

**Very rare (affects less than 1 in 10,000 people)**

- Persistent painful erection usually unrelated to sexual activity.
- Rash, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (Stevens-Johnson syndrome).
- Abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), difficult breathing (dyspnoea).

The following side effects have also been reported:

**Common (affects less than 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 (affects less than 1 in 100 people)**

- weakness
- headache
- runny or blocked nose

- dizziness as you sit or stand up
- palpitations (rapid or irregular heart beat)
- gastro-intestinal symptoms such as nausea and vomiting (feeling or being sick), diarrhoea or constipation
- hypersensitivity reactions such as rash, itching, redness, local swelling and breathing problems

**Rare (affects less than 1 in 1000 people)**

- fainting

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

- blurred vision
- impaired vision
- nose bleeds (epistaxis)
- serious skin rashes (erythema multiforme, dermatitis exfoliative)
- dry mouth

As with other medicines of this type, drowsiness, blurred vision or swelling of the hands and feet can occur.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

**e) How to store FLOEZY**

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 carton (EXP).

The expiry date refers to the last day of that month.

Store below 30°C in the original package.

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.

**f) Further information**

**What FLOEZY contains**

The active substance is tamsulosin hydrochloride. Each prolonged release tablet contains 0.400mg tamsulosin hydrochloride which is equivalent to 0.367 mg of tamsulosin.

The other ingredients are Hypromellose cellulose microcrystalline, Carbomer, Silica colloidal anhydrous, Iron oxide red.

**What FLOEZY looks like and contents of the pack**

White, un-scored, round tablets with a diameter of 9mm debossed on one side with “T9SL” and “0.4” on the other side.

FLOEZY is available as packs of 3X10's.

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