

## TAMCONTIN 0.4 (CONTROLLED RELEASE TABLETS OF TAMSULOSIN)

### PACKAGE LEAFLET: INFORMATION FOR THE USER

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**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, health care provider or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms 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 health care provider or pharmacist.

#### **What is in this leaflet?**

1. What Tamcontin 0.4 is and what it is used for?
2. What you need to know before you take Tamcontin 0.4?
3. How to take Tamcontin 0.4?
4. Possible side effects?
5. How to store?
- 6 Contents of the pack and other information

#### **1. What Tamcontin 0.4 tablets is and what it is used for?**

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The active ingredient of Tamcontin 0.4 is Tamsulosin Hydrochloride 0.4 mg. Tamsulosin is an alpha1A-adrenoreceptor blocker. It relaxes the muscles in the prostate and urinary tract.

Tamcontin 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 help in urination.

#### **2. What you need to know before you take Tamcontin 0.4 tablets?**

##### **Do not take Tamcontin 0.4 mg 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-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**

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.

if you suffer from **severe kidney problems**. The normal dose of tamsulosin may not have the expected effect when your kidneys are not functioning normally.

if you are undergoing **eye surgery** because of cloudiness of the lens (cataract). An eye condition called Intraoperative Floppy Iris Syndrome may occur, please inform your eye specialist that you are using or have previously used 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 of the eye (glaucoma).

Before starting therapy with tamsulosin, your doctor should examine you to confirm your symptoms are truly caused by an enlarged prostate.

### **Children and adolescents**

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

### **Taking Other medicines with Tamcontin 0.4 tablets.**

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  $\alpha$ 1-adrenoreceptor blocker**. The combination may lower your blood pressure, causing dizziness or light-headedness.
- Ketoconazole**, a medicine to treat fungal skin infections. This medicine may increase the effect of Tamsulosin.

Tell your doctor **or pharmacist** if you are taking, have recently taken or might use any of the medicines.

### **Tamcontin 0.4 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 and breast-feeding**

Tamsulosin is not indicated for use in women.

### **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 Tamcontin 0.4 Tablets?**

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Always take these tablets exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure. Swallow your tablets whole with a glass of water.

Dosage of 0.4 mg once daily is recommended for the treatment of signs and symptoms of benign prostatic hyperplasia (BPH). The tablet is to be swallowed whole and not crushed or chewed. It should be administered approximately at half an hour following the same meal each day.

For those patients who fail to respond to the 0.4 mg dose after two to four weeks of dosing, the dose of Tamsulosin tablets can be increased to 0.8 mg once daily. If therapy is discontinued or interrupted for several days at either the 0.4 mg or 0.8 mg dose, therapy should be started again with the 0.4 mg once daily dose.

### **If you take more Tamcontin 0.4 tablets than recommended**

Your blood pressure may suddenly drop if you take more Tamsulosin than you should. You may experience dizziness, weakness, and fainting, vomiting and diarrhoea. 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 fluid level and may 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 Tamcontin 0.4 tablets**

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

### **If you stop taking Tamcontin 0.4 tablets**

When treatment with Tamcontin is stopped prematurely, your original complaints may return. Therefore, use Tamsulosin 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 reactions are very rare. **Contact your doctor immediately** if you experience:

**A serious allergic reaction which causes swelling of the face or throat (angio-oedema).** You should not be restarted on Tamsulosin.

#### **Common side effects (may affect up to 1 in 10 people)**

Dizziness, particularly when going to sit or stand up.

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).

#### **Uncommon side effects (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 • Hives (urticaria) • Feeling of weakness (asthenia) • Itching.

#### **Rare side effects (may affect up to 1 in 1,000 people)**

Fainting (syncope)

**Very rare side effects** (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 side effects (frequency cannot be estimated from the available data)**

Blurred vision • Vision loss • Nosebleeds (epistaxis) • Dry mouth • Serious skin rashes (erythema multiforme, dermatitis exfoliative) • Abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), difficult breathing (dyspnoea)

During eye surgery because of cloudiness of the lens (cataract) or increased pressure in the eye (glaucoma) 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.

### **5. How to store Tamcontin 0.4 Tablets?**

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

Store at or below 25° C, in a dry place, protected from light.

Do not use this medicine after the expiry date which is stated on the carton.

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

### **6. Other information**

#### **What Tamcontin 0.4 Tablets contains?**

- Tamcontin 0.4: Each enteric-coated tablet contains: Tamsulosin Hydrochloride BP: 0.4 mg (In a Continus controlled release system).
- The other ingredients are Cetostearyl Alcohol, Lactose, Povidone K-30, Magnesium Stearate, Microcrystalline Cellulose, Hydroxyethylcellulose, Purified Talc, Acryl-Eze 93 O 18359 White, Purified Water

#### **What Tamcontin 0.4 tablets looks like and contents of the pack?**

**Tamcontin 0.4:** White to off-white, round, biconvex, enteric-coated tablets with ‘.4’ engraved on one of the facets.

**Tamcontin 0.4:** Box of 100 Tablets (10x10’s strips)

#### **Manufactured by:**

Modi-Mundipharma Pvt. Ltd.

Modipuram – 250 110

U.P., India

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