

TALUSIN® **0.4 mg Capsules**

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about TALUSIN

Each modified-release capsule of TALUSIN for oral administration contains 0.4 mg tamsulosin hydrochloride.

TALUSIN capsules are for use by men only.

Tamsulosin is an alpha₁-adrenoreceptor blocking agent that exhibits selectivity for alpha₁ receptors in the human prostate.

TALUSIN capsules are indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in adult men.

Benign prostatic hyperplasia is an enlargement of the prostate, the gland located below the bladder. As the prostate enlarges, it may slowly restrict the flow of urine. Symptoms of BPH include weak or interrupted urinary stream, difficulty urinating, urgency and need to urinate often especially at night, incomplete emptying of the bladder.

TALUSIN capsules act by relaxing muscles in the prostate and bladder neck at the site of the obstruction, resulting in improved urine flow and reduced BPH symptoms.

The way to take TALUSIN

Take TALUSIN as directed by your physician.

The usual recommended dose is one capsule of 0.4 mg, once daily. It should be administered approximately 30 minutes following the same meal each day.

For those patients who fail to respond to the 0.4 mg dose after 2 to 4 weeks of treatment, the dose can be increased to 0.8 mg (2 capsules of 0.4 mg) once daily.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

If you miss a dose, take it as soon as you remember. Do not take an extra dose to make up for missed doses. If you miss a day, just continue to take your daily dose as prescribed.

Contraindications

This drug is contraindicated in patients known to be hypersensitive to any of the components.

Precautions

- Periodic medical examinations are necessary during long-term use of this drug.
- A sudden drop in blood pressure can occur especially following the first dose or when changing doses of the drug. Such a drop in blood pressure, although rare in occurrence, may be associated with fainting, dizziness or lightheadedness. Caution should be used when driving, operating machinery or performing hazardous tasks.
- This drug should be used with caution in case of severe hepatic or renal impairment.
- Inform your ophthalmologist that you are taking this drug before undergoing cataract surgery.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

This drug should not be used with other alpha-adrenergic blocking agents.

This drug should be used with caution when administered concomitantly with cimetidine or warfarin.

Adverse reactions

The most reported adverse reactions include: headache, fatigue, dizziness, palpitations, orthostatic hypotension, rhinitis, diarrhea, vomiting, abnormal ejaculation, and allergic reactions.

Extremely rarely, this drug and similar medications have caused priapism, a persistent painful erection of the penis which requires immediate medical treatment. Inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

TALUSIN, tamsulosin HCl 0.4 mg, pack of 30 modified release capsules

Issue date: 06/2008

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