

PATIENT INFORMATION

Tamsulosin Hydrochloride (tam soo' loe sin hye" droe klor' ide) Capsules, USP 0.4 mg

Read the Patient Information that comes with tamsulosin hydrochloride capsules before you start taking it and each time you refill your prescription. The information may have changed. This leaflet does not take the place of discussions with your doctor about your medical condition or your treatment.

What are tamsulosin hydrochloride capsules ?

Tamsulosin hydrochloride capsules are a prescription alpha-blocker medicine used to treat the signs and symptoms of benign prostatic hyperplasia (BPH), a condition your doctor may refer to as an enlarged prostate.

- Tamsulosin hydrochloride capsules are not for women.
- Tamsulosin hydrochloride capsules are not for children.

Who should not take tamsulosin hydrochloride capsules?

Do not take tamsulosin hydrochloride capsules if you are allergic to any of its ingredients. See the end of this leaflet for a complete list of ingredients in tamsulosin hydrochloride capsules .

What should I tell my doctor before using tamsulosin hydrochloride capsules ?

Before taking tamsulosin hydrochloride capsules, tell your doctor about all your medical conditions, including:

- any kidney or liver problems.
- any history of low blood pressure.
- any allergies to sulfa or any other medicines.
- if you are planning to have cataract or glaucoma surgery.

Tell your doctor about all the medicines you take, including:

- any prescription medicines, including blood pressure medicines.
- any non-prescription medicines, including vitamins and herbal supplements.

Some of your other medicines may affect the way tamsulosin hydrochloride capsules work. Especially tell your doctor if you take a medicine for high blood pressure. You should not take tamsulosin hydrochloride capsules if you are already taking certain blood pressure medicines.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take tamsulosin hydrochloride capsules ?

- Take tamsulosin hydrochloride capsules exactly as prescribed by your doctor.
- Do not crush, chew, or open tamsulosin hydrochloride capsules .
- Take tamsulosin hydrochloride capsules one time each day, about 30 minutes after the same meal each day. For example, you may take tamsulosin hydrochloride capsules 30 minutes after dinner each day.
- If you miss a dose of tamsulosin hydrochloride capsules , take it as soon as you remember. If you miss your dose for the whole day, continue with your next dose on your regular schedule. Do not take two doses at the same time.
- If you stop or forget to take tamsulosin hydrochloride capsules for several days, talk with your doctor before starting again.
- If you take more tamsulosin hydrochloride capsules than prescribed, call your doctor right away.

What are the possible side effects of tamsulosin hydrochloride capsules?

Possible side effects of tamsulosin hydrochloride capsules may include:

- **Decreased blood pressure when changing positions.** Tamsulosin hydrochloride capsules may cause a sudden drop in blood pressure upon standing, especially after the first dose or when changing doses.

Symptoms may include:

- fainting
- dizziness
- lightheadedness

Change positions slowly from lying down to sitting up or from a sitting to a standing position until you learn how you react to tamsulosin hydrochloride capsules . If you begin to feel dizzy, sit or lie down until you feel better. If the symptoms are severe or do not improve, call your doctor.

- **Allergic reactions.** Make your doctor aware of any allergic reactions you may experience while taking tamsulosin hydrochloride capsules .

Allergic reactions may include:

- rash
- itching
- hives

Rare and more serious allergic reactions may also occur. **Get medical help right away if you have any of the following reactions:**

- swelling of face, tongue, or throat
- difficulty breathing
- blistering of the skin

- **A painful erection that will not go away.** Tamsulosin hydrochloride capsules can cause a painful erection (priapism), which cannot be relieved by having sex. If this happens, get medical help right away. If priapism is not treated, you may not be able to get an erection in the future.

- **Eye problems during cataract or glaucoma surgery.** During cataract or glaucoma surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you take or have taken tamsulosin hydrochloride capsules. If you need to have cataract or glaucoma surgery, be sure to tell your surgeon if you take or have taken tamsulosin hydrochloride capsules.

Common side effects of tamsulosin hydrochloride capsules may include:

- runny nose
- dizziness
- decreased semen

These are not all the possible side effects with tamsulosin hydrochloride capsules . Tell your doctor if you have any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088, or by visiting www.fda.gov/medwatch.

What should I avoid while taking tamsulosin hydrochloride capsules?

Avoid driving, operating machinery, or other dangerous activities, until you know how tamsulosin hydrochloride capsules affects you. Tamsulosin hydrochloride capsules may cause a sudden drop in blood pressure upon standing, especially after the first dose or when changing doses. See "**What are the possible side effects of tamsulosin hydrochloride capsules?**"

How do I store tamsulosin hydrochloride capsules?

Store tamsulosin hydrochloride capsules at room temperature 68°F to 77°F (20°C to 25°C). Short-term exposure to higher or lower temperatures [from 59°F (15°C) to 86°F (30°C)] is acceptable. Ask your doctor or pharmacist if you have any questions about storing your capsules.

Keep tamsulosin hydrochloride capsules and all medicines out of the reach of children.

General information

This medicine was prescribed for you by your doctor for your condition. Do not use it for another condition. Do not give tamsulosin hydrochloride capsules to other people, even if they have the same symptoms that you have. It may harm them.

While taking tamsulosin hydrochloride capsules, you must have regular checkups. Follow your doctor's advice about when to have these checkups.

BPH can occur with other more serious conditions, including prostate cancer. Therefore, ask your doctor about screening for prostate cancer prior to treatment with tamsulosin hydrochloride capsules and at regular intervals afterwards.

This patient information leaflet summarizes the most important information about tamsulosin hydrochloride capsules . If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about tamsulosin hydrochloride capsules that is written for health professionals. For more information call Ascend Laboratories LLC at 1-877-ASC-RX01 (877-272-7901).

What are the ingredients in tamsulosin hydrochloride capsules?

Active Ingredient: tamsulosin hydrochloride, USP

Inactive Ingredients: microcrystalline cellulose, Eudragit L30D-55 dispersion, hypromellose, triacetin , calcium stearate, talc, iron oxide red, iron oxide yellow, FD&C blue 2, titanium dioxide, gelatin and trace amounts of black edible ink (containing: shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, black iron oxide and potassium hydroxide).

Manufactured by:

Alkem Laboratories Ltd.,
INDIA.

Distributed by:

Ascend Laboratories, LLC
Parsippany, NJ 07054

Revised: November, 2021