

## PATIENT INFORMATION

### Dutasteride (doo tas' ter ide) and Tamsulosin Hydrochloride (tam soo' loe sin hye'' droe klor' ide) Capsules

**Dutasteride and tamsulosin hydrochloride capsules are for use by men only.**

#### **What are dutasteride and tamsulosin hydrochloride capsules?**

Dutasteride and tamsulosin hydrochloride capsules are a prescription medicine that contains 2 medicines: dutasteride and tamsulosin. Dutasteride and tamsulosin hydrochloride capsules are used to treat the symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate. The 2 medications in dutasteride and tamsulosin hydrochloride capsules work in different ways to improve symptoms of BPH. Dutasteride shrinks the enlarged prostate and tamsulosin relaxes muscles in the prostate and neck of the bladder. These 2 medications, when used together, can improve symptoms of BPH better than either medication when used alone.

#### **Do not take dutasteride and tamsulosin hydrochloride capsules if you are:**

- pregnant or may be pregnant. Dutasteride and tamsulosin hydrochloride capsules may harm your unborn baby. Pregnant females should not touch dutasteride and tamsulosin hydrochloride capsules. If a female who is pregnant with a male baby gets enough dutasteride and tamsulosin hydrochloride capsules in her body by swallowing or touching dutasteride and tamsulosin hydrochloride capsules, the male baby may be born with sex organs that are not normal. If a pregnant female comes in contact with leaking dutasteride and tamsulosin hydrochloride capsules, the contact area should be washed immediately with soap and water.
- allergic to dutasteride, tamsulosin, or any of the ingredients in dutasteride and tamsulosin hydrochloride capsules. See the end of this leaflet for a complete list of ingredients in dutasteride and tamsulosin hydrochloride capsules.
- taking another medicine that contains an alpha-blocker.
- allergic to other 5-alpha-reductase inhibitors, for example, PROSCAR (finasteride) tablets.

#### **Before you take dutasteride and tamsulosin hydrochloride capsules, tell your healthcare provider about all of your medical conditions, including if you:**

- have a history of low blood pressure
- take medicines to treat high blood pressure
- plan to have cataract or glaucoma surgery
- have liver problems
- are allergic to sulfa medications
- have any other medical conditions

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Dutasteride and tamsulosin hydrochloride capsules and other medicines may affect each other, causing side effects. Dutasteride and tamsulosin hydrochloride capsules may affect the way other medicines work, and other medicines may affect how dutasteride and tamsulosin hydrochloride capsules work.

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

#### **How should I take dutasteride and tamsulosin hydrochloride capsules?**

- Take dutasteride and tamsulosin hydrochloride capsules exactly as your healthcare provider tells you to take it.
- Swallow dutasteride and tamsulosin hydrochloride capsules whole. Do not crush, chew, or open dutasteride and tamsulosin hydrochloride capsules because the contents of the capsule may irritate your lips, mouth, or throat.
- Take your dutasteride and tamsulosin hydrochloride capsules 1 time each day, about 30 minutes after the same meal every day. For example, you may take dutasteride and tamsulosin hydrochloride capsules 30 minutes after dinner every day.
- If you miss a dose, you can take it later that same day, 30 minutes after a meal. Do not take 2 dutasteride and tamsulosin hydrochloride capsules in the same day. If you stop or forget to take dutasteride and tamsulosin hydrochloride capsules for several days, talk with your healthcare provider before starting again.
- If you take too much dutasteride and tamsulosin hydrochloride capsules, call your healthcare provider or go to the nearest hospital emergency room right away.

#### **What should I avoid while taking dutasteride and tamsulosin hydrochloride capsules?**

- Avoid driving, operating machinery, or other dangerous activities when starting treatment with dutasteride and tamsulosin hydrochloride capsules until you know how dutasteride and tamsulosin hydrochloride capsules affects you. Dutasteride and tamsulosin hydrochloride capsules can cause a sudden drop in your blood pressure, especially at the start of treatment. A sudden drop in blood pressure may cause you to faint, feel dizzy or lightheaded.
- You should not donate blood while taking dutasteride and tamsulosin hydrochloride capsules or for 6 months after you have stopped dutasteride and tamsulosin hydrochloride capsules. This is important to prevent pregnant females from receiving dutasteride and tamsulosin hydrochloride capsules through blood transfusions.

#### **What are the possible side effects of dutasteride and tamsulosin hydrochloride capsules?**

##### **Dutasteride and tamsulosin hydrochloride capsules may cause serious side effects including:**

- **Decreased blood pressure.** Dutasteride and tamsulosin hydrochloride capsules may cause a sudden drop in your blood pressure upon standing from a sitting or lying position, especially at the start of treatment. Symptoms of low blood pressure may include:
  - fainting
  - dizziness
  - feeling lightheaded
- **Rare and serious allergic reactions, including:**
  - swelling of your face, tongue, or throat
  - difficulty breathing
  - serious skin reactions, such as skin peeling

Get medical help right away if you have these serious allergic reactions.

- **Higher chance of a more serious form of prostate cancer.**
- **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 dutasteride and tamsulosin hydrochloride capsules in the past. If you need to have cataract or glaucoma surgery, tell your surgeon if you take or have taken dutasteride and tamsulosin hydrochloride capsules.
- **A painful erection that will not go away.** Rarely, dutasteride and 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, there could be lasting damage to your penis, including not being able to have an erection.

The most common side effects of dutasteride and tamsulosin hydrochloride capsules include:

- ejaculation problems\*
- trouble getting or keeping an erection (impotence)\*
- a decrease in sex drive (libido)\*
- dizziness
- enlarged or painful breasts. If you notice breast lumps or nipple discharge, you should talk to your healthcare provider.
- runny nose

\*Some of these events may continue after you stop taking dutasteride and tamsulosin hydrochloride capsules.

Depressed mood has been reported in patients receiving dutasteride, an ingredient of dutasteride and tamsulosin hydrochloride capsules.

Dutasteride, an ingredient of dutasteride and tamsulosin hydrochloride capsules, has been shown to reduce sperm count, semen volume, and sperm movement. However, the effect of dutasteride and tamsulosin hydrochloride capsules on male fertility is not known.

**Prostate-Specific Antigen (PSA) Test:** Your healthcare provider may check you for other prostate problems, including prostate cancer before you start and while you take dutasteride and tamsulosin hydrochloride capsules. A blood test called PSA (prostate-specific antigen) is sometimes used to see if you might have prostate cancer. Dutasteride and tamsulosin hydrochloride capsules will reduce the amount of PSA measured in your blood. Your healthcare provider is aware of this effect and can still use PSA to see if you might have prostate cancer. Increases in your PSA levels while on treatment with dutasteride and tamsulosin hydrochloride capsules (even if the PSA levels are in the normal range) should be evaluated by your healthcare provider. These are not all the possible side effects with dutasteride and tamsulosin hydrochloride capsules. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **How should I store dutasteride and tamsulosin hydrochloride capsules?**

- Store dutasteride and tamsulosin hydrochloride capsules at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
- Dutasteride and tamsulosin hydrochloride capsules may become deformed and/or discolored if kept at high temperatures.
- Do not use or touch dutasteride and tamsulosin hydrochloride capsules if your capsules are deformed, discolored, or leaking.
- Safely throw away medicine that is no longer needed.

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

#### **General information about the safe and effective use of dutasteride and tamsulosin hydrochloride capsules.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use dutasteride and tamsulosin hydrochloride capsules for a condition for which it was not prescribed. Do not give dutasteride and tamsulosin hydrochloride capsules to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about dutasteride and tamsulosin hydrochloride capsules that is written for health professionals.

For more information, call 1-800-828-9393.

#### **What are the ingredients in dutasteride and tamsulosin hydrochloride capsules?**

**Active ingredients:** dutasteride and tamsulosin hydrochloride

**Inactive ingredients:** butylated hydroxytoluene, ethylcellulose, gelatin, glycerin, lecithin, medium chain triglycerides, methacrylic acid copolymer, mono- and di-glycerides of capryl/capric acid, polyethylene glycol, sugar spheres, talc, triethyl citrate, iron oxide yellow, hypromellose, titanium dioxide, D&C yellow #10, iron oxide black, FD&C blue #2, FD&C blue #1, propylene glycol, FD&C red #40, shellac, polyvinyl acetate phthalate, macrogol, ammonium hydroxide.

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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