

  
**Patient Information**  
**Dutasteride Capsules**  
**(doo tas' ter ide)**

**Dutasteride capsules are for use by men only.**

Read this patient information before you start taking dutasteride and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

**What is Dutasteride?**

Dutasteride capsules are a prescription medicine that contains dutasteride. Dutasteride is used to treat the symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate to:

- improve symptoms
- reduce the risk of acute urinary retention (a complete blockage of urine flow)
- reduce the risk of the need for BPH-related surgery

**Who should NOT take dutasteride capsules?**

**Do Not Take dutasteride capsules if you are:**

- pregnant or could become pregnant. Dutasteride capsules may harm your unborn baby. Pregnant women should not touch dutasteride capsules. If a woman who is pregnant with a male baby gets enough dutasteride in her body by swallowing or touching dutasteride, the male baby may be born with sex organs that are not normal. If a pregnant woman or woman of childbearing potential comes in contact with leaking dutasteride capsules, the contact area should be washed immediately with soap and water.
- a child or a teenager.
- allergic to dutasteride or any of the ingredients in dutasteride capsules. See the end of this leaflet for a complete list of ingredients in dutasteride capsules.
- allergic to other 5 alpha-reductase inhibitors, for example, finasteride tablets.

**What should I tell my healthcare provider before taking dutasteride capsules?**

**Before you take dutasteride capsules, tell your healthcare provider if you:**

- have liver problems

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

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 capsules?**

- Take 1 dutasteride capsule once a day.
- Swallow dutasteride capsules whole. Do not crush, chew, or open dutasteride capsules because the contents of the capsule may irritate your lips, mouth, or throat.
- You can take dutasteride with or without food.
- If you miss a dose, you may take it later that day. Do not make up the missed dose by taking 2 doses the next day.

**What should I avoid while taking dutasteride?**

- You should not donate blood while taking dutasteride capsules or for 6 months after you have stopped dutasteride capsules. This is important to prevent pregnant women from receiving dutasteride capsules through blood transfusions.

**What are the possible side effects of dutasteride?**

**Dutasteride capsule may cause serious side effects, including:**

- **Rare and serious allergic reactions, including:**
  - swelling of your face, tongue, or throat
  - 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.**

The most common side effects of dutasteride capsule include:

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

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

Depressed mood has been reported in patients receiving dutasteride capsules.

Dutasteride capsules has been shown to reduce sperm count, semen volume, and sperm movement. However, the effect of dutasteride 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 capsules. A blood test called PSA (prostate-specific antigen) is sometimes used to see if you might have prostate cancer. Dutasteride 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 capsules (even if the PSA levels are in the normal range) should be evaluated by your healthcare provider.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects with dutasteride capsules. For more information, ask your healthcare provider or pharmacist.

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 capsules?**

- Store dutasteride capsules at room temperature (20° to 25°C or 68°F to 77°F).
- Dutasteride capsules may become deformed and/or discolored if kept at high temperatures.
- Do not use dutasteride capsules if your capsules are deformed, discolored, or leaking.
- Safely throw away medicine that is no longer needed.

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

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

This patient information leaflet summarizes the most important information about dutasteride capsules. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about dutasteride capsules that is written for health professionals.

For more information on dutasteride capsules, go to [www.exelanpharma.com](http://www.exelanpharma.com) or call 1-855-295-7455.

#### **What are the ingredients in dutasteride capsules?**

**Active ingredient:** dutasteride.

**Inactive ingredients:** butylated hydroxytoluene, ferric oxide (yellow), gelatin (from certified BSE-free bovine sources), glycerin, mono-di-glycerides of caprylic/capric acid, titanium dioxide. The capsules are printed with edible black ink containing black iron oxide, hypromellose and propylene glycol.

#### **How does dutasteride capsules work?**

Prostate growth is caused by a hormone in the blood called dihydrotestosterone (DHT). Dutasteride capsules lowers DHT production in the body, leading to shrinkage of the enlarged prostate in most men. While some men have fewer problems and symptoms after 3 months of treatment with dutasteride capsules, a treatment period of at least 6 months is usually necessary to see if dutasteride capsule will work for you.

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