

PATIENT INFORMATION
Dutasteride Capsules
(doo tas' ter ide)

Dutasteride capsules are for use by men only.

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.

Prostate growth is caused by a hormone in the blood called dihydrotestosterone (DHT). Dutasteride 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, a treatment period of at least 6 months is usually necessary to see if dutasteride will work for you.

Do not take dutasteride capsules if you are:

- pregnant or may be 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 comes in contact with leaking dutasteride capsules, the contact area should be washed immediately with soap and water.
- 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, PROSCAR (finasteride) tablets.

Before you take dutasteride capsules, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter 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 capsules?

- 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 capsules?

Dutasteride capsules 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 peelingGet 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 capsules 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.

These are not all the possible side effects of dutasteride 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 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.

General information about the safe and effective use of dutasteride capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information 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.

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

For more information call 1-866-495-1995.

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.

Manufactured by:

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Manufactured for:

XLCare Pharmaceuticals, Inc.

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

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