

Patient Information

Finasteride Tablets, USP (fin as' ter ide)

Finasteride tablets are for use by **MEN ONLY** and should **NOT** be used by women or children.

Read this Patient Information before you start taking finasteride tablets 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 treatment.

What are finasteride tablets?

Finasteride tablets are a prescription medicine used for the treatment of male pattern hair loss (androgenetic alopecia).

It is not known if finasteride tablets work for a receding hairline on either side of and above your forehead (temporal area).

Finasteride tablets are not for use by women and children.

Who should not take finasteride tablets?

Do not take finasteride tablets if you:

- are pregnant or may become pregnant. Finasteride tablets may harm your unborn baby.
 - Finasteride tablets are coated and will prevent contact with the medicine during handling, as long as the tablets are not broken or crushed. Females who are pregnant or who may become pregnant should not come in contact with broken or crushed finasteride tablets. If a pregnant woman comes in contact with crushed or broken finasteride tablets, wash the contact area right away with soap and water. If a woman who is pregnant comes into contact with the active ingredient in finasteride tablets, a healthcare provider should be consulted.
 - If a woman who is pregnant with a male baby swallows or comes in contact with the medicine in finasteride tablets, the male baby may be born with sex organs that are not normal.
- are allergic to any of the ingredients in finasteride tablets. See the end of this leaflet for a complete list of ingredients in finasteride tablets.

What should I tell my healthcare provider before taking finasteride tablets?

Before taking finasteride tablets, tell your healthcare provider if you:

- have any other medical conditions, including problems with your prostate or liver

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

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 finasteride tablets?

- Take finasteride tablets exactly as your healthcare provider tells you to take them.
- You may take finasteride tablets with or without food.
- If you forget to take finasteride tablets, do not take an extra tablet. Just take the next tablet as usual.

Finasteride tablets will not work faster or better if you take them more than once a day.

What are the possible side effects of finasteride tablets?

- **decrease in your blood Prostate Specific Antigen (PSA) levels.** Finasteride tablets can affect a blood test called PSA (Prostate Specific Antigen) for the screening of prostate cancer. If you have a PSA test done you should tell your healthcare provider that you are taking finasteride tablets because finasteride tablets decreases PSA levels. Changes in PSA levels will need to be evaluated by your healthcare provider. Any increase in follow-up PSA levels from their lowest point may signal the presence of prostate cancer and should be evaluated, even if the test results are still within the normal range for men not taking finasteride tablets. You should also tell your healthcare provider if you have not been taking finasteride tablets as prescribed because this may affect the PSA test results. For more information, talk to your healthcare provider.
- There may be an increased risk of a more serious form of prostate cancer in men taking finasteride at 5 times the dose of finasteride tablets.

The most common side effects of finasteride tablets include:

- decrease in sex drive
- trouble getting or keeping an erection
- a decrease in the amount of semen

The following have been reported in general use with finasteride tablets:

- breast tenderness and enlargement. Tell your healthcare provider about any changes in your breasts such as lumps, pain or nipple discharge.
- depression;
- decrease in sex drive that continued after stopping the medication;
- allergic reactions including rash, itching, hives and swelling of the lips, tongue, throat, and face;
- problems with ejaculation that continued after stopping medication;
- testicular pain;
- difficulty in achieving an erection that continued after stopping the medication;
- male infertility and/or poor quality of semen.
- in rare cases, male breast cancer.

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 of finasteride tablets. 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 finasteride tablets?

- Store finasteride tablets at 20° to 25°C (68° to 77°F).
- Keep finasteride tablets in a closed container and keep finasteride tablets dry (protect from moisture).

Keep finasteride tablets and all medicines out of the reach of children.

General information about the safe and effective use of finasteride tablets.

Medicines are sometimes prescribed for purposes other than those listed in this Patient Information leaflet. Do not use finasteride tablets for a condition for which it was not prescribed. Do not give finasteride tablets to other people, even if they have the same symptoms you have. They may harm them.

This Patient Information leaflet summarizes the most important information about finasteride tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about finasteride tablets that is written for health professionals. For more information, **call 1-866-850-2876**.

What are the ingredients in finasteride tablets?

Active ingredient: finasteride.

Inactive ingredients: docusate sodium, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch (maize), sodium starch glycolate, talc, and titanium dioxide.

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

Manufactured for:

Burel Pharmaceuticals, LLC

Mason, OH 45040 USA

Manufactured by:

Aurobindo Pharma Limited

Hyderabad-500 090, India

Revised: 08/2022