

Module 1.3	Product Information	Version: 2016-09-01
Module 1.3.1	Package Leaflet	Replaces : 2014-08-29

Package Leaflet: Information for the patient**Dutasteride Apotex 0.5 mg capsules, soft
Dutasteride**

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Dutasteride Apotex is and what it is used for
2. What you need to know before you take Dutasteride Apotex
3. How to take Dutasteride Apotex
4. Possible side effects
5. How to store Dutasteride Apotex
6. Contents of the pack and other information

1. What Dutasteride Apotex is and what it is used for

Dutasteride Apotex is used to treat men with an enlarged prostate (benign prostatic hyperplasia) - a non-cancerous growth of the prostate gland, caused by producing too much of a hormone called dihydrotestosterone.

As the prostate grows, it can lead to urinary problems, such as difficulty in passing urine and a need to go to the toilet frequently. It can also cause the flow of the urine to be slower and less forceful. If left untreated, there is a risk that your urine flow will be completely blocked (acute urinary retention). This requires immediate medical treatment. In some situations surgery is necessary to remove or reduce the size of the prostate gland. Dutasteride Apotex lowers the production of dihydrotestosterone, which helps to shrink the prostate and relieve the symptoms. This will reduce the risk of acute urinary retention and the need for surgery.

The active ingredient is dutasteride. It belongs to a group of medicines called 5-alpha reductase inhibitors.

Dutasteride Apotex may also be taken with another medicine called tamsulosin (used to treat the symptoms of an enlarged prostate).

2. What you need to know before you take Dutasteride Apotex**Do not take Dutasteride Apotex**

- if you are allergic to dutasteride or any of the other ingredients of this medicine (listed in section 6)

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- if you are allergic to any 5-alpha reductase inhibitors other than dutasteride
- if you have a severe liver disease.

Tell your doctor if you think any of these apply to you and do NOT take Dutasteride Apotex.

This medicine is for men only. It must not be taken by women, children or adolescents.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dutasteride Apotex.

- In some clinical studies, more patients taking dutasteride and another medicine called an alpha-blocker, like tamsulosin, experienced heart failure than patients taking only dutasteride or only an alpha-blocker. Heart failure means your heart does not pump blood as well as it should.
- **Make sure your doctor knows about liver problems.** If you have had any illness affecting your liver, you may need some additional check-ups while you are taking Dutasteride Apotex.
- **Women, children and adolescents** must not handle leaking Dutasteride Apotex capsules, because the active ingredient can be absorbed through the skin. **Wash the affected area immediately** with soap and water if there is any contact with the skin.
- **Use a condom during sexual intercourse.** Dutasteride has been found in the semen of men taking Dutasteride Apotex. If your partner is or may be pregnant, you must avoid exposing her to your semen as dutasteride may affect the normal development of a male baby. Dutasteride has been shown to decrease sperm count, semen volume and sperm motility. This could reduce your fertility (see section “Pregnancy, breast-feeding and fertility”).
- **Dutasteride Apotex affects a blood test for PSA** (prostate-specific antigen), which is sometimes used to detect prostate cancer. Your doctor should be aware of this effect and can still use the test to detect prostate cancer. If you are having a blood test for PSA, tell your doctor that you are taking Dutasteride Apotex. Men taking Dutasteride Apotex should have their PSA tested regularly.
- In a clinical study of men at increased risk of prostate cancer, men taking Dutasteride Apotex had a **serious form of prostate cancer more often** than men who did not take Dutasteride Apotex. The effect of Dutasteride Apotex on this serious form of prostate cancer is not clear.
- **Dutasteride Apotex may cause breast enlargement and tenderness.** If this becomes troublesome, or if you notice **breast lumps or nipple discharge** you should talk to your doctor about these changes as these may be signs of a serious condition, such as breast cancer.

Contact your doctor or pharmacist if you have any questions about taking Dutasteride Apotex.

Other medicines and Dutasteride Apotex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can react with Dutasteride Apotex and may make it more likely that you will have side-effects. These medicines include:

- **verapamil or diltiazem** (for high blood pressure)
- **ritonavir or indinavir** (for HIV)
- **itraconazole or ketoconazole** (for fungal infections)
- **nefazodone** (an antidepressant)
- **alpha-blockers** (for enlarged prostate or high blood pressure).

Tell your doctor if you are taking any of these medicines. Your dose of Dutasteride Apotex may need to

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be reduced.

Dutasteride Apotex with food and drink

Dutasteride Apotex can be taken with or without food.

Pregnancy, breast-feeding and fertility

Women who are pregnant (or may be) must not handle leaking capsules. Dutasteride is absorbed through the skin and can affect the normal development of a male baby. This is a particular risk in the first 16 weeks of pregnancy.

Use a condom during sexual intercourse. Dutasteride has been found in the semen of men taking Dutasteride Apotex. If your partner is or may be pregnant or could become pregnant, you must avoid exposing her to your semen.

Dutasteride Apotex has been shown to reduce sperm count, semen volume and sperm movement. Therefore male fertility may be reduced.

Contact your doctor for advice if a pregnant woman has come into contact with dutasteride.

Driving and using machines

Dutasteride Apotex is unlikely to affect your ability to drive or operate machinery.

3. How to take Dutasteride Apotex

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Always take this medicine regularly. If you do not take it regularly the monitoring of your PSA levels may be affected (see section 2 “Warnings and precautions”).

How much to take

The recommended dose is one capsule (0.5 mg) taken once a day. Swallow the capsules whole with water. Do not chew or break open the capsule. Contact with the contents of the capsules may make your mouth or throat sore.

Dutasteride Apotex is a **long-term** treatment. Some men notice an early improvement in their symptoms. However, others may need to take this medicine for 6 months or more before it begins to have an effect. Keep taking Dutasteride Apotex for as long as your doctor tells you.

If you take more Dutasteride Apotex than you should

Contact your doctor or pharmacist for advice if you take too many capsules.

If you forget to take Dutasteride Apotex

Do not take extra capsules to make up for a missed dose. Just take your next dose at the usual time.

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If you stop taking Dutasteride Apotex

Do not stop taking this medicine without talking to your doctor first. It may take up to 6 months or more for you to notice an effect.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reaction

The signs of allergic reactions can include:

- **skin rash** (which can be itchy)
- **hives** (like a nettle rash)
- **swelling of the eyelids, face, lips, arms or legs.**

Contact your doctor immediately if you get any of these symptoms, and **stop taking Dutasteride Apotex.**

Common side effects

These may affect up to 1 in 10 men:

- not able to achieve or maintain an erection (impotence), this may continue after you stop taking dutasteride
- decreased sex drive (libido), this may continue after you stop taking dutasteride
- difficulty with ejaculation, this may continue after you stop taking dutasteride
- breast enlargement or tenderness (gynecomastia)
- dizziness when taken with tamsulosin.

Uncommon side effects

These may affect up to 1 in 100 men:

- heart failure (your heart becomes less efficient at pumping blood around the body. You may have symptoms such as shortness of breath, extreme tiredness and swelling in your ankles and legs).
- hair loss (usually from the body) or hair growth.

Not known side effects

The frequency cannot be estimated from the available data:

- depressed mood
- pain and swelling in your testicles

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system listed in Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

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5. How to store Dutasteride Apotex

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Store in the original package, in order to protect from light.

Do not use this medicine after the expiry date which is stated after 'EXP' on the carton and blister. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dutasteride Apotex contains

The active substance is dutasteride. Each soft capsule contains 0.5 mg dutasteride.

The other ingredients are:

- Inside the capsule: glycerol monocaprylocaprate, butylhydroxytoluene (E321).
- Capsule shell: gelatin, glycerol, purified water, iron oxide yellow (E172), titanium dioxide (E171).
- Printing ink: shellac glaze, iron oxide red (E172), isopropyl alcohol, n-butyl alcohol, propylene glycol, ammonium hydroxide, simethicone.

What Dutasteride Apotex looks like and contents of the pack

Dutasteride Apotex soft capsules are an oily, colourless to pale yellow liquid within a pale yellow, oblong gelatin capsule (16.3 mm x 6.4 mm) marked on one side "APO", opposing side "D 0.5".

They are available in PVC/PVdC/Al blister packs of 30, 90 or 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

<[To be completed nationally]>

Manufacturer:

<[To be completed nationally]>

<*Distributor:*

[To be completed nationally]>

This leaflet was last revised in: {MM/YYYY}