

Dutasteride 0.5mg
soft capsules

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Dutasteride is and what it is used for

Dutasteride contains the active substance dutasteride, which belongs to a group of medicines called 5-alpha reductase inhibitors.

Dutasteride 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 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.

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

2. What you need to know before you take Dutasteride

Do not take Dutasteride:

- if you are allergic to dutasteride, other 5-alpha reductase, soya, peanut or any of the other ingredients of this medicine (listed in section 6).
- if you have severe liver disease.

If you think any of these apply to you, don't take this medicine until you have checked with your doctor.

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

Warnings and precautions

Talking with your doctor or pharmacist
Talk to your doctor or pharmacist before taking Dutasteride.

- If you have or have had any other liver problem. You may need some additional check-ups while you are taking Dutasteride.
- 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. (See Pregnancy, breast-feeding and fertility section below). You must use a condom during sexual intercourse while on treatment with Dutasteride.

Women, children and adolescents must not handle leaking Dutasteride, 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 (See pregnancy, breast-feeding and fertility section).

During treatment

During treatment

Tell your doctor, if you suffer from heart failure (inability of your heart to pump blood as well as it should which include signs such as shortness of breath, swelling in the arms or legs, persistent cough or wheezing) while taking Dutasteride. The risk of heart failure is greater if you are taking another medicine called an alpha-blocker, like tamsulosin along with dutasteride.

Your doctor may carry out frequent tests to check the risk of developing prostate cancer before and during treatment with Dutasteride. Although the effect of Dutasteride on prostate cancer is not clear, studies have show that men taking dutasteride had a serious form of prostate cancer more often than men who did not take dutasteride.

Tell your doctor if you notice 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.

Laboratory tests

Laboratory tests
If you need to have a blood test called “PSA (prostate specific antigen)”. Tell your doctor or nurse that you are taking Dutasteride as dutasteride may alter the results of the test. Men taking Dutasteride should have their PSA tested regularly.

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

Other medicines and Dutasteride

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

Some medicines can react with Dutasteride and may make it more likely that you'll 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 may need to be reduced.

Pregnancy, breast-feeding and fertility

Dutasteride must not be used by women (see 'Do not take Dutasteride' section above).

Pregnancy

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. If your partner is or may be pregnant, you must avoid exposing her to your semen.

Fertility

Dutasteride 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

Driving and using machines
Dutasteride is unlikely to affect your ability to drive or operate machinery.

Dutasteride contains Allura red AC aluminium lake (E129)

This medicine contains allura red AC aluminium lake (E129) which may cause allergic reactions. If you are allergic to allura red AC aluminium lake (E129) do not take this medicine.

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Description		Dutasteride 0.5 mg 30		Date: 24 Nov 16		Time: 01:56	
Component Type	Leaflet	Pharma Code	N/A	No. of colours	1	Page Count	1 / 2
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Packing Site/Printer	Cipla Ltd (Pune - IN)	Client Market	Ireland	Dimensions	150 x 430 mm	Min Text Size used	9 pt
Supplier Code	N/A	Keyline/Drawing No.	150 x 430 mm Dutasteride 0.5mg MYLAN Capsule PIL				
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Sign-offs							
v1/May 2015							

