

PACKAGE LEAFLET: INFORMATION FOR THE USER

DUTAPROST

0.5mg Capsules, soft

DUTASTERIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Dutaprost Capsules are and what they are used for
2. What you need to know before you take Dutaprost Capsules
3. How to take Dutaprost Capsules
4. Possible side effects
5. How to store Dutaprost Capsules

1. WHAT DUTAPROST CAPSULES ARE AND WHAT THEY ARE USED FOR

Dutaprost Capsules are 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.

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

Dutaprost Capsules 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 DUTAPROST CAPSULES

Do not take Dutaprost Capsules:

- if you are allergic to dutasteride, other 5-alpha reductase inhibitors, lecithin, soya, peanut or any of the other ingredients of this medicine.
- if you have severe liver disease.

Tell your doctor if you think any of these apply to you.

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 Dutaprost Capsules

- 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 Dutaprost Capsules.
- Women, children and adolescents must not handle leaking Dutaprost 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 Dutaprost Capsules. 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.
- Dutaprost Capsules 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 Dutaprost Capsules. Men taking Dutaprost Capsules should have their PSA tested regularly. In a clinical study of men at increased risk of prostate cancer, men taking Dutaprost Capsules had a serious form of prostate cancer more often than men who did not take Dutaprost Capsules. The effect of Dutaprost Capsules on this serious form of prostate cancer is not clear.
- Dutaprost Capsules 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 Dutaprost Capsules.

Other medicines and Dutaprost Capsules

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

Some medicines can react with Dutaprost Capsules 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 Dutaprost Capsules may need to be reduced.

Dutaprost Capsules with food and drink

Dutaprost Capsules can be taken with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

Dutaprost Capsules are unlikely to affect your ability to drive or operate machinery.

Dutaprost Capsules contains lecithin

This medicine contains lecithin from soya, which may contain soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

3. HOW TO TAKE DUTAPROST CAPSULES

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

If you do not take it regularly the monitoring of your PSA levels may be affected. Check with your doctor or pharmacist if you are not sure.

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

If you take more Dutaprost Capsules than you should

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

If you forget to take Dutaprost Capsules

Do not take a double dose to make up for a forgotten dose, just take your next dose at the usual time.

If you stop taking Dutaprost Capsules

Don't stop taking Dutaprost Capsules 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 using Dutaprost Capsules.

Common side effects

These may affect up to 1 in 10 men taking Dutaprost Capsules:

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

Uncommon side effects

These may affect up to 1 in 100 men taking Dutaprost Capsules:

- heart failure (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 the 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DUTAPROST CAPSULES

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

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton or foil blister strip after Exp. 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.

This leaflet was last revised in June 2015.