

Package leaflet: Information for the user

Dutasteride 0.5 mg soft capsules

Dutasteride

Read all of this leaflet carefully before you start using 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 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 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.

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. 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 inhibitors, lecithin, soya, peanut or any of the other ingredients of this medicine (listed in section 6).
- 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 Dutasteride

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

Other medicines and Dutasteride

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.

Dutasteride with food and drink

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

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

Dutasteride 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 Dutasteride

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

If you take more Dutasteride than you should

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

If you forget to take Dutasteride

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 Dutasteride

Don't stop taking Dutasteride 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 Dutasteride.**

Common side effects

These may affect up to 1 in 10 men taking Dutasteride:

- impotence (*not able to achieve or maintain an erection*), 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 taking Dutasteride:

- 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. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: + 353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store Dutasteride

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.

6. Contents of the pack and other information

What Dutasteride contains

- **The active substance is dutasteride.** Each soft capsule contains 0.5 mg dutasteride
- The other ingredients are:
 - inside the capsule: glyceryl monocaprylocaprate type I, (capmul MCM, NF (mono- and di-glycerides, NF), butylhydroxytoluene (E321).
 - capsule shell: gelatin (E441), glycerol (E422), titanium dioxide (E171), iron oxide yellow (E172), lecithin from soy (E322).
 - printing ink: shellac glaze in ethanol, iron oxide black (E172), propylene glycol (E1520), ammonium hydroxide (E527).

What Dutasteride looks like and contents of the pack

Dutasteride soft capsules are yellow, opaque, oblong capsules 16.65 mm x 6.68 mm, filled with clear transparent oily solution, imprinted with “2632” in black ink. They are available in blister packs of 10, 30, 50, 60 and 90 capsules. Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Actavis Group PTC ehf.

Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland

Manufacturer

Pharmadox Healthcare Ltd. KW20A,
Corradino Industrial Estate Paola,
PLA 3000,
Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Dutasteride Accord Healthcare
Austria	Dutasterid Accord Healthcare 0,5 mg Weichkapseln
Bulgaria	Dutasteride Accord Healthcare
Cyprus	Dutasteride Accord Healthcare
Czech Republic	Dutasterid Accord Healthcare 0,5 mg
Estonia	Dutasteride Accord Healthcare
Greece	Dutasteride / Accord Healthcare
Finland	Dutasteride Accord Healthcare
Croatia	CAMINARD 0,5 mg meke kapsule
Ireland	Dutasteride 0.5 mg Soft Capsules
Iceland	Dutasteride Accord Healthcare
Lithuania	Dutasteride Accord Healthcare 0,5 mg minkštosios kapsulės
Latvia	Dutasteride Accord Healthcare 0,5 mg mīkstās kapsulas
Malta	Dutasteride Accord Healthcare
Norway	Dutasteride Accord Healthcare
Poland	Dutasteride Accord Healthcare
Romania	Dutasterida Accord Healthcare 0,5 mg capsule moi
Slovenia	Dutasteride Accord Healthcare 0,5 mg mehke kapsule
United Kingdom	Dutasteride 0.5 mg Capsules, soft

This leaflet was last revised in September 2018