

Dutasteride 0.5 mg 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 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 in men to treat:

- moderate to severe symptoms of an **enlarged prostate**, which is a non-cancerous growth of the prostate gland. Dutasteride decreases the risk of suddenly being unable to pass urine and needing surgery. It may be used alone or combined with another medicine called tamsulosin.

Dutasteride belongs to a group of medicines called 5-alpha reductase inhibitors. It lowers the production of dihydrotestosterone, which helps to shrink the prostate and relieve symptoms. Prostate enlargement can lead to problems such as difficulty in passing urine and more frequently urination. It can also reduce the force of urine flow. If left untreated, there is a risk of completely blocked urine flow.

2 What you need to know before you take Dutasteride

Do not take Dutasteride

if you are

- **allergic** to dutasteride or any of the other ingredients of this medicine (listed in section 6);
- affected by a **severe liver disease**
- **female**
- **a child or adolescent**

Warnings and precautions

Talk to your doctor or pharmacist before taking Dutasteride if the following apply to you:

- **liver problems**
Additional check-ups may be required during Dutasteride treatment if you have had any liver problem. Do not take Dutasteride if you have a severe liver disease. See under "Do not take Dutasteride".
- need a blood test for **PSA**, a protein produced in the prostate gland. Your doctor should be aware that Dutasteride affects this test. This test can still be used to detect prostate cancer, but a new baseline for this protein must be considered. Men taking Dutasteride should have their PSA tested regularly.
- increased **risk of prostate cancer**
- **breast enlargement and tenderness** during treatment. Talk to your doctor if you notice breast lumps, nipple discharge or any breast changes. These may be signs of a serious condition, such as breast cancer.

Women, children and adolescents must **not handle leaking Dutasteride capsules**, as 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. See under "Pregnancy, breast-feeding, fertility".

Children and adolescents

Dutasteride must not be taken by children or adolescents.

Other medicines and Dutasteride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The following medicines can react with Dutasteride and make side effects more likely:

- medicines to treat enlarged prostate or high blood pressure called alpha-blockers, such as **tamsulosin**
- **verapamil, diltiazem**: medicines to treat high blood pressure and heart disorders
- **ritonavir, indinavir**: medicines to treat HIV infections
- **itraconazole, ketoconazole**: medicines to treat fungal infections
- **nefazodone**: a medicine to treat depression

Pregnancy, breast-feeding and fertility

Women must not take Dutasteride.

Women must not handle leaking capsules, especially during the first 16 weeks of pregnancy. Dutasteride is absorbed through the skin and can affect the normal development of a male baby.

Use a condom during sexual intercourse as dutasteride has been found in the semen of men taking this medicine. If your partner is or may be pregnant, you must avoid exposing her to your semen. Contact your doctor for advice if a pregnant woman has come into contact with dutasteride.

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

Driving and using machines

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

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.

The recommended dose is 1 capsule once daily.

Method of use

Swallow the capsules whole with one glass of water at the same time of the day. The capsule can be taken with or without food.

Do not chew or break open the capsule as contact with capsule contents may make your mouth or throat sore.

Duration of use

Take Dutasteride for as long as your doctor tells you. Dutasteride use 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. If you do not take it regularly the results of treatment may be reduced.

If you take more Dutasteride than you should

Contact your doctor or pharmacist for advice.

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

Do not stop Dutasteride use without your doctor's permission, as this can reduce the therapy 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.

Contact your doctor immediately and stop taking Dutasteride if you get any of these allergic reaction symptoms (Frequency not known: cannot be estimated from available data):

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

Other side effects can occur with the following frequencies:

Common, may affect up to 1 in 10 people

- unable to achieve or maintain an erection, this may continue after you stop taking Dutasteride
- decreased sex drive, this may continue after you stop taking Dutasteride
- difficulty ejaculating, this may continue after you stop taking Dutasteride
- breast enlargement or tenderness
See chapter 2, under "Warnings and precautions"
- dizziness, when also taking tamsulosin

Uncommon, may affect up to 1 in 100 people

- reduced heart function
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

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.

Tel: +353 1 6764971, Fax: +353 1 6762517,

Website: www.imb.ie

e-mail: imbpharmacovigilance@imb.ie

5 How to store Dutasteride

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

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

This medicinal product does not require any special storage conditions.

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 capsule, soft contains 0.5 mg of dutasteride.

The other ingredients are:

- glycerol monocaprylocaprate (type I)
- butylhydroxytoluene (E321)
- gelatin
- glycerol
- titanium dioxide (E171)
- iron oxide yellow (E172)
- citric acid, anhydrous
- glycine
- shellac Glaze (modified)
- iron oxide black (E 172)
- propylene Glycol (E1520)
- ammonium Hydroxide 28% (E527)

What Dutasteride looks like and contents of the pack

The capsules are beige to yellow, oblong soft gelatin capsule of 6.8 mm with black imprint "D0.5", with welding seam. Dutasteride is supplied in: PVC/PVCD//AL blister containing: 10, 30, 50, 60, 90 and 100 capsules, soft.

HDPE bottles with PP cap child-resistant closure containing: 10, 30, 50, 60, 90 and 100 capsules, soft.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers:

Lek Pharmaceuticals d.d., Verovškova 57, 1526

Ljubljana, Slovenia.

LEK S.A., ul. Domaniewska 50 C, 02-672 Warszawa,

Poland.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1,

39179 Barleben, Germany.

S.C. Sandoz, S.R.L, Str. Livezeni nr. 7A, RO-540472

Targu-Mures, Romania.

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

AT: Dutasterid Sandoz 0,5 mg – Weichkapseln

BE: Dutasterid Sandoz, 0.5 mg Capsules, soft

BG: Dutasteride Sandoz

CZ: Dutasteride Sandoz 0,5 mg

DE: Dutasterid – 1 A Pharma 0,5 mg

Weichkapseln ENR: 2188765

DK: Dutasteride Sandoz

ES: Dutasterida Sandoz 0,5 mg cápsulas blandas

EFG

FI: Dutasteride Sandoz

FR: DUTASTERIDE SANDOZ 0,5 mg, capsule

molle

IE: Dutasteride 0.5 mg soft capsules

IT: DUTASTERIDE SANDOZ

LT: Quedute 0,5 mg minkštosios capsules

LU: Dutasterid Sandoz, 0.5 mg Capsules Molles

NL: Dutasteride Sandoz 0,5 mg, capsules, zacht

PT: Dutasterida Sandoz

RO: Dutasterida Sandoz 0,5 mg capsule moi

SE: Dutasteride Sandoz

SI: Dutasterid Lek 0,5 mg mehke kapsule

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