

Package leaflet: Information for the user  
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 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 in this medicine 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** or to any of the other ingredients of this medicine (listed in section 6).
- **if you have a severe liver disease.**

➤ **Tell your doctor** 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

Talk to your doctor before taking Dutasteride.

- **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.

Children and adolescents

Dutasteride should not be taken by children and adolescents.

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 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 may need to be reduced.

Dutasteride with food and drink

Dutasteride can be taken with or without food.

Pregnancy, breast-feeding and fertility

**Women who are (or may be) pregnant 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 this medicine. 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 allura red

This medicine contains allura red which may cause allergic reactions. If you are allergic to allura red, do not take this medicinal product.

3. How to take Dutasteride

**Always take this medicine exactly as your doctor 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.

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 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 Dutasteride more 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.

**Do not stop taking Dutasteride without advice**  
Do not 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 reactions**  
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.

**Common side effects** (may affect up to 1 in 10 people)

- not being 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** (may affect up to 1 in 100 people)

- heart becomes less efficient at pumping blood around the body (heart failure). 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** (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  
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

Store this medicine at temperatures below 25°C.

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 carton/label. 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 contain**

- The active substance is dutasteride. Each soft capsule contains 0.5 mg dutasteride.
- The other ingredients are:

*Capsule contents:*  
- butylated hydroxytoluene (E321), mono and diglycerides of caprylic/capric acid

*Capsule shell:*  
- gelatine, glycerol, titanium dioxide (E171), iron oxide yellow (E172),

*Printing Ink:*  
- allura red AC aluminium lake (E129), propylene glycol (E1520), hypromellose (E464) and titanium dioxide (E171)

**What Dutasteride look like and contents of the pack**  
Clear oily colourless solution encapsulated in yellow coloured, opaque, oblong shaped soft gelatin capsules of 19.7 mm ± 1.5 mm length and 6.70 mm ± 1 mm width, with "DU" imprinted with red ink along the length of body on one side of capsule

Your capsules will come in packs of:  
Blisters of white opaque PVC/PVDC/Aluminium film containing 10 soft gelatin capsules packed into containers of 10, 30, 50, 60 and 90 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorization Holder:  
**Cipla Europe NV**  
De Keyserlei 58-60, Box-19, 2018 Antwerp, Belgium

Manufacturer  
**S&D Pharma CZ, spol. s r.o**  
spol. s r.o, Theodor 28, 273 08 Pchery (Pharmos a.s. facility), Czech republic

**Cipla (EU) Limited**  
Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom

**Cipla Europe NV**  
De Keyserlei 58-60, Box-19, 2018, Antwerp, Belgium

**Pharmadox Healthcare Limited**  
KW20A Corradino Industrial Estate,  
Paola PLA 3000,  
Malta

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

Member State	Product Name
United kingdom	Dutasteride 0.5 mg soft capsules
Bulgaria	Дутастерид Сипла 0,5 mg меки капсули
Czech Republic	Dutasteride Cipla 0,5 mg, měkké tobolky
Denmark	Dutasteride Orion 0,5 mg bløde kapsler
Germany	Dutasterid Cipla 0,5 mg Weichkapseln
Greece	Dutasteride Cipla 0,5 mg μαλακά καψάκια
Spain	Dutasterida Cipla 0,5 mg cápsulas blandas EFG
Finland	Dutasteride Orion
France	Dutasteride Mylan Pharma 0,5 mg, capsule molle
Ireland	Dutasteride 0.5 mg soft capsules
Italy	Dutasteride Cipla
Malta	Dutasteride 0.5 mg soft capsules
Netherlands	Dutasteride Cipla 0,5 mg, zachte capsules
Norway	Dutasteride Cipla 0,5 mg myke kapsler
Portugal	Dutasterida Cipla 0,5 mg cápsulas moles
Poland	Dutasteride Cipla, 0,5 mg, kapsułki, miękkie
Romania	Dutasterida Cipla 0,5 mg capsule moi
Slovakia	Dutasterid Cipla 0,5 mg mäkké kapsuly

This leaflet was last revised in 10/2017.