

## Package leaflet: Information for the patient

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

#### 1. What Dutasteride capsule is and what it is used for

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

**Dutasteride capsule 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 capsule 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 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 Dutasteride capsules

##### Do not take Dutasteride capsules

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

Talk to your doctor before taking Dutasteride capsules:

- **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 capsules.
- **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 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.
- **Dutasteride 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 Dutasteride capsules. **Men taking Dutasteride capsules should have their PSA tested regularly.**
- In a clinical study of men at increased risk of prostate cancer, men taking Dutasteride capsules had a **serious form of prostate cancer more often** than men who did not take Dutasteride capsules. The effect

of Dutasteride capsules on this serious form of prostate cancer is not clear.

- **Dutasteride 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 Dutasteride capsules.

#### **Other medicines and Dutasteride capsules**

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

Some medicines can react with Dutasteride 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 Dutasteride capsules may need to be reduced.

#### **Dutasteride capsules with food and drink**

Dutasteride capsules can be taken with or without food.

#### **Pregnancy, breast-feeding and fertility**

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

Dutasteride 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**

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

#### **Dutasteride capsules contains lecithin from soya**

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 capsules**

**Always take this medicine exactly as your doctor or pharmacist has told you to.** 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 capsule is a long term treatment. Some men notice an early improvement in their symptoms. However, others may need to take Dutasteride capsules for 6 months or more before it begins to have an effect. Keep taking Dutasteride capsules for as long as your doctor tells you.

#### **If you take more Dutasteride capsules than you should**

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

#### **If you forget to take Dutasteride capsules**

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

#### **Don't stop taking Dutasteride capsules without advice**

Don't stop taking Dutasteride 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 Dutasteride capsules.**

##### Common side effects

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

- not able to achieve or maintain an erection (impotence) \*this may continue after you stop taking Dutasteride capsules
- decreased sex drive (libido) this may continue after you stop taking Dutasteride capsules
- difficulty with ejaculation , such as a decrease in the amount of semen released during sex, this may continue after you stop taking Dutasteride capsules
- breast enlargement or tenderness (gynecomastia)
- dizziness when taken with tamsulosin

##### Uncommon side effects

*These may affect up to 1 in 100 men taking Dutasteride Accord:*

- 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:

- depression 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 Yellow Card Scheme ,

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Dutasteride capsules

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 and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original container to protect from moisture.

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 capsules contains

The active substance is dutasteride.

Each soft capsule contains 0.5 mg dutasteride.

The other ingredients are:

- inside the capsule: glycerol monocaprylocaprate (type I), butylhydroxytoluene (E321).
- capsule shell: gelatine, glycerol, titanium dioxide (E171), iron oxide yellow (E172), triglycerides (medium chain), soya lecithin (E-322) and purified water.

##### What Dutasteride capsules looks like and contents of the pack

Dutasteride capsules soft capsules are size 6, oblong opaque and yellow, soft gelatin capsules containing an oily and yellowish liquid. They are available in blister packs of 10, 30, 50, 60, 90 capsules and perforated blister packs of 10x1, 30x1, 50x1, 60x1 and 90x1 capsule. Not all pack sizes may be marketed.

Soft capsules dimensions are:  $19 \pm 0.8$  mm x  $6.9 \pm 0.4$  mm.

##### Marketing Authorisation Holder and Manufacturer

##### Marketing Authorisation Holder:

Accord Healthcare Limited  
Sage House, 319 Pinner Road, North Harrow  
Middlesex, HA1 4HF  
United Kingdom

**Manufacturer:**

Cyndeia Pharma S.L.  
Polígono Industrial Emiliano Revilla Sanz  
Avenida de Ágreda,31  
Olvega, 42110 Soria  
Spain

Galenicum Health S.L.  
Avda. Cornellá 144, 7º-1ª, Edificio LEKLA  
Esplugues de Llobregat  
08950 Barcelona  
Spain

Accord Healthcare Limited  
Sage House, 319 Pinner Road, North Harrow  
Middlesex, HA1 4HF  
United Kingdom

Pharmadox Healthcare Ltd  
KW20A Kordin Industrial Park, Paola  
PLA 3000, Malta

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