

Package leaflet: Information for the patient

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

1. What Avodart is and what it is used for

Avodart 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. Avodart 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.

Avodart 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 Avodart

Do not take Avodart

- **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 Avodart.

- **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 Avodart.
- **Women, children and adolescents** must not handle leaking Avodart 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 Avodart. 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.

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

- **Avodart 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.

Mood changes and depression

- Depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients taking another medicine from the same therapeutic class (5-alpha reductase inhibitor) by mouth. If any of these symptoms occur, contact your doctor for further medical advice as soon as possible.

➔ **Contact your doctor or pharmacist** if you have any questions about taking Avodart.

Other medicines and Avodart

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

Some medicines can react with Avodart 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 Avodart may need to be reduced.

Avodart with food and drink

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

Avodart 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

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

Avodart 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 Avodart

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

If you take more Avodart than you should

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

If you forget to take Avodart

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 Avodart without advice

Don't stop taking Avodart 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 Avodart.**

Common side effects

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

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

Uncommon side effects

These may affect up to 1 in 100 men taking Avodart:

- 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
- 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, Website: www.hpra.ie.

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

5. How to store Avodart

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

Do not store Avodart above 30° C.

Don't use this medicine after the expiry date which is stated on the carton or the foil blister strip. The expiry date refers to the last day of that month.

The expiry dates on the Spanish and Italian blisters are denoted by 'CAD' and 'SCAD' respectively.

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 Avodart contains

The active substance is dutasteride. Each soft capsule contains 0.5 mg dutasteride.

The other ingredients are:

- inside the capsule: mono and diglycerides of caprylic/capric acid and butylated hydroxytoluene (E321)
- capsule shell: gelatin, glycerol, titanium dioxide (E171), iron oxide yellow (E172), triglycerides (medium chain), lecithin (may contain soya oil).
- printed ink: iron oxide red (E172) as the colourant, polyvinyl acetate phthalate, propylene glycol and macrogol.

What Avodart looks like and contents of the pack

Avodart soft capsules are oblong opaque, yellow, soft gelatin capsules printed with GX CE2 on one side in red ink. They are available in packs of 30 capsules.

Manufacturer

GlaxoSmithKline Pharmaceuticals S.A. ul. Grunwaldzka 189, 60-322 Poznan, Poland or Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany or Delpharm Poznan S.A., ul. Grunwaldzka 189, 60 - 322 Poznan, Poland.

Product is imported from within the EU, repackaged and distributed by the Parallel Product Authorisation holder: PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland

Parallel Product Authorisation number: PPA0465/211/001

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Avidart – Spain

This leaflet was last revised in June 2026