

PACKAGE LEAFLET: INFORMATION FOR THE USER

Avodart® 0.5mg soft capsules

(dutasteride)

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- **If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

The name of your medicine is Avodart 0.5mg soft capsules but will be referred to as Avodart throughout this leaflet.

In this leaflet:

1. What Avodart is and what it's used for
2. Before you take Avodart
3. How to take Avodart
4. Possible side effects
5. How to store Avodart
6. Further information

1 WHAT AVODART IS AND WHAT IT'S 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 BEFORE YOU TAKE AVODART

Do not take Avodart

- if **you're allergic (hypersensitive) to dutasteride, other 5-alpha reductase inhibitors, soya, peanut** or to any of the other ingredients of Avodart.
- **if you have a 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.

Take special care with Avodart

- 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 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 affect 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.

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

Taking other medicines

Tell your doctor if you're taking, or have recently taken, any other medicines. This includes any medicines you've bought without a prescription.

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.

Food and drink with Avodart

Avodart can be taken with or without food.

Pregnancy and breast-feeding

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.

Important information about some of the ingredients of Avodart

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 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 usual dose is one capsule (0.5mg) 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 too much Avodart

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

If you forget to take Avodart

Don't take extra capsules to make up for a missed 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.

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4 POSSIBLE SIDE EFFECTS

Like all medicines, Avodart 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, 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:

- depressed mood
- pain and swelling in your testicles

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Keep out of the sight and reach of children.

Do not use Avodart after the expiry date which is stated on the carton and blister label after 'Exp'. The expiry date refers to the last day of that month.

Do not store Avodart above 30°C.

If you have any unwanted Avodart, don't dispose of them in waste water or household rubbish. Take them back to your pharmacist, who will dispose of them in a way that won't harm the environment.

6 FURTHER INFORMATION

Each soft capsule contains 0.5mg dutasteride.

The other ingredients are:

- capsule contents: mono and diglycerides of caprylic/capric acid and butylhydroxytoluene (E321).
- capsule shell: gelatin, glycerol, titanium dioxide (E171), iron oxide yellow (E172), triglycerides (medium chain), lecithin.

What Avodart looks like and contents of the pack

Avodart are oblong opaque, yellow, soft gelatin capsules printed with 'GX CE2'. They are available in blister packs of 30 capsules in an over labelled cardboard carton.

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Procured from within the EU and repackaged by the PPA holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK

Avodart® 0.5mg Soft Capsules

PPA: 1328/134/1

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