

Package leaflet: information for the patient

Avodart 0.5 mg soft capsules

dutasteride

Read the entire 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.
- Do you have any questions? Contact your doctor, pharmacist, or nurse.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, pharmacist, or nurse.

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1. What is Avodart and what is it used for?

Avodart is used to treat men with a condition called benign prostatic hyperplasia or BPH. This is a non-cancerous enlargement of the prostate, caused by an excessive production of the hormone "dihydrotestosterone".

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

If the prostate enlarges, it can lead to urinary problems, such as difficulty urinating and the need to urinate frequently. An enlarging prostate can also cause a slower and less powerful urine stream. If left untreated, there is a risk that your urine stream will be completely blocked (acute urinary retention). Such a blockage requires immediate medical treatment. In some situations, surgery is needed to remove or reduce the size of the prostate. This medicine reduces the production of dihydrotestosterone. This causes the prostate to shrink and your symptoms to lessen. This also reduces the risk of acute urinary retention and the need for surgery.

This medicine can also be prescribed together with another medicine that contains tamsulosin as an active ingredient. Tamsulosin is prescribed to reduce symptoms caused by an enlarged prostate.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to dutasteride, other 5-alpha-reductase inhibitors, soy, peanuts, or any of the other ingredients in this medicine. You can find these ingredients in section 6.

- You have a severe liver disease.

If you suspect that one or more of the above points apply to you, do not use this medicine and contact your doctor.

This medicine is intended for men only and should not be used by women, children, and adolescents.

When should you be extra careful with this medicine?

Talk to your doctor before using this medicine.

- Make sure your doctor is aware of any potential liver problems. If you have (had) a liver disease, it may be necessary for you to be monitored more closely while using this medicine.
- Women, children, and adolescents should avoid any contact with leaking capsules, as the active ingredient dutasteride is absorbed through the skin. Wash the contact area immediately with water and soap if skin contact occurs.
- Use a condom when having sexual intercourse. Dutasteride has been found in the semen of men taking this medicine. If your partner is pregnant or could become pregnant, you should prevent her from being exposed to your semen because dutasteride can affect the normal development of a male baby. It has been shown that dutasteride reduces sperm count, semen volume, and sperm motility. This could reduce your fertility.
- This medicine affects the outcome of the PSA test (Prostate-Specific Antigen test). This test is sometimes used to check for prostate cancer. Your doctor is aware of this influence and can still use this test to investigate prostate cancer. If you are having a PSA test, you should tell your doctor that you are using this medicine. Men using this medicine should have their PSA levels checked regularly.
- In a clinical study of men at increased risk of prostate cancer, men taking this medicine were more likely to have a severe form of prostate cancer than men not taking this medicine. The effect of this medicine on this severe form of prostate cancer is not clear.
- This medicine can cause breast enlargement and tenderness. If this becomes bothersome, or if you notice lumps in the breast or nipple discharge, contact your doctor about these changes as they may indicate a serious condition, such as breast cancer.

Mood changes and depression

- A low mood, depression, and, less commonly, suicidal thoughts have been reported in patients taking another medicine from the same group of medicines (5-alpha-reductase inhibitors) orally. If any of these complaints occur, contact your doctor as soon as possible for further medical advice.

Contact your doctor or pharmacist if you have questions about using this medicine.

Are you taking any other medicines?

Do you use any other medicines besides Avodart, have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

Some medicines can interact with this medicine and this may increase the chance of side effects. These include the medicines:

- verapamil or diltiazem (for the treatment of high blood pressure)
- ritonavir or indinavir (for the treatment of HIV infection)
- itraconazole or ketoconazole (for the treatment of fungal infections)
- nefazodone (for the treatment of depression)
- alpha-blockers (for the treatment of an enlarged prostate or high blood pressure)

Tell your doctor if you are using any of the above medicines. It may be necessary to reduce the dose of Avodart.

What should you pay attention to with food and drink?

This medicine can be taken with or without food.

Pregnancy, breastfeeding, and fertility

Women, especially those who are pregnant or may become pregnant, should avoid any contact with leaking capsules. Dutasteride is absorbed through the skin and can affect the normal development of a male baby. This is particularly a risk in the first sixteen weeks of pregnancy.

Use a condom when you have sexual intercourse. Dutasteride has been found in the semen of men taking this medicine. If your partner is pregnant or could become pregnant, you should prevent her from being exposed to your semen.

It has been shown that dutasteride reduces sperm count, semen volume, and sperm motility. This could reduce male fertility.

Contact your doctor for advice if a pregnant woman has been in contact with dutasteride.

Driving and using machines

It is unlikely that this medicine will affect your ability to drive or operate machines.

Avodart contains lecithin derived from soy

Avodart contains lecithin derived from soy and may contain soybean oil. If you are allergic to peanuts or soy, you should not use this medicine.

3. How do you use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you do not use it regularly, it may affect the control of your PSA levels. Unsure about the correct use? Then contact your doctor or pharmacist.

Dosage

The recommended dosage is one capsule (0.5 mg) per day. Swallow the capsules whole with water. Do not bite or open the capsules. Contact with the contents of the capsules can lead to irritation of your mouth or throat.

Treatment with this medicine is long-term. Some men notice an improvement in their symptoms quickly, but others may need to continue treatment for up to six months or longer before an effect is noticeable. Use this medicine for as long as your doctor has prescribed it.

Have you used too much of this medicine?

If you have taken too many capsules of this medicine, ask your doctor or pharmacist for advice.

Have you forgotten to use this medicine?

Do not take a double dose to make up for a forgotten dose. Take the next dose according to the usual schedule.

If you stop using this medicine

Do not stop taking this medicine without consulting your doctor. It may take up to six months or longer before you notice an effect.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Allergic side effects

The following symptoms may occur with these allergic reactions:

- skin rash (possibly with itching)
- hives (look like nettle rash)
- swelling of eyelids, face, lips, arms, or legs

Contact your doctor immediately if any of these symptoms occur and stop using this medicine.

Common side effects

These side effects occur in less than 1 in 10 users:

- Not able to get or maintain an erection (impotence). This may persist after you stop using this medicine
- reduced
- interest in sex (loss of libido). This may persist after you stop using this medicine
- problems
- with ejaculation, such as a decreased amount of semen released during sexual intercourse. This may persist after you stop using this medicine
- breast formation
- with enlargement and/or tenderness around the breast gland (gynecomastia)
- dizziness
- when used with tamsulosin

Occasionally occurring side effects

These side effects occur in less than 1 in 100 users:

- heart failure (the heart becomes less efficient at pumping blood around the body. You may experience shortness of breath, extreme fatigue, and swelling of the ankles and legs)

- hair loss (usually from the body) or hair growth

Not known

The frequency of these side effects cannot be determined from the available data:

- depression
- pain and swelling in your testicles

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Store below 30°C.

Do not use this medicine after the expiry date. You can find it on the carton and on the blister pack after EXP. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

6. Contents of the pack and other information

What substances are in this medicine?

The active substance in this medicine is dutasteride. Each soft capsule contains 0.5 mg of dutasteride.

The other substances in this medicine are:

- capsule contents: mono- and diglycerides of caprylic acid and capric acid and butylated hydroxytoluene (E321)
- capsule shell: gelatin, glycerol, titanium dioxide (E171), yellow iron oxide (E172), triglycerides (medium-chain), lecithin (may contain soybean oil)

What does Avodart look like and what is in a pack?

Avodart soft capsules are oblong, opaque, yellow, soft gelatin capsules, marked with GX CE2. They are available in packs of 10, 30, 50, 60, and 90 capsules. Not all pack sizes may be marketed.

Registered under RVG number 28317.

Marketing authorization holder and manufacturer

Marketing authorization holder:

GlaxoSmithKline BV
Van Asch van Wijckstraat 55H
3811 LP Amersfoort
033 2081100

Manufacturer:

Delpharm Poznań Spółka Akcyjna
Ul. Grunwaldzka 189
60-322 Poznan
Poland

Or

Aspen Bad Oldesloe GmbH
Industriestrasse 32-36
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Germany

This medicine is registered in EEA member states under the following names:

Avodart - Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Sweden, Netherlands, United Kingdom
Avidart – Spain

This leaflet was last approved in August 2025.