

LEAFLET: INFORMATION FOR THE PATIENT

Avodart, soft capsules 0.5 mg
dutasteride

Read the entire leaflet carefully before you start using 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 only for you. 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.

Contents of this leaflet

1. What is Avodart and what is it used for?
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1. WHAT IS AVODART AND WHAT IS IT USED FOR?

Avodart is used for the treatment of 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 medication 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 medication 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 CAUTIOUS?

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 cautious 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 must 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 have a PSA test, you must tell your doctor that you are using this medicine. Men using this medicine should have their PSA checked regularly.
- In a clinical study of men at increased risk of prostate cancer, men taking this medicine were more likely to have a serious form of prostate cancer than men not taking this medicine. The effect of this medicine on this serious 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.

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

Are you taking any other medicines?

Are you using 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 may increase the risk 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 during the first sixteen weeks of pregnancy.

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.

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 TO 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.

Are you unsure about the correct usage? 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 the 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 (appear as 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:

- unable to get or maintain an erection (impotence). This may persist after you stop using this medicine.
- reduced desire for sex (loss of libido). This may persist after you stop using this medicine.
- problems with ejaculation, such as a decreased sperm volume released during sexual intercourse. This may persist after you stop using this medicine.
- breast 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 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 any 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 label on the packaging 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 then be destroyed responsibly and will not enter the environment.

6. CONTENTS OF THE PACKAGING 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 butylhydroxytoluene (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 package?

Avodart soft capsules are oblong, opaque, yellow, soft gelatin capsules, marked with GX CE2. They are available in packs of 30 capsules.

Marketing authorization holder and manufacturer

Euro Registratie Collectief b.v.

Kempkens 2200

5465 PR Veghel

Repacker (see label on the outer packaging):

Brocacef B.V., Marostraat 43, 1060 LG Amsterdam

or

Stephar B.V., Kempkens 2200, 5465 PR Veghel

Manufacturers:

Delpharm Poznań Spółka Akcyjna

Ul. Grunwaldzka 189

60-322 Poznań Poland

or

Aspen Bad Oldesloe GmbH

Industriestrasse 32-36

23843 Bad Oldesloe

Germany

Registered under

RVG 32039//28317 Avodart, soft capsules 0.5 mg (Italy)

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