

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986**

The medicine is dispensed according to a physician's prescription only

## Avodart soft capsules

Each soft capsule contains: 0.5 mg Dutasteride.

For a list of the inactive and allergenic ingredients, see section 2 "Important information about some ingredients of the medicine" and section 6 "Additional information".

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is intended for men only.

### 1. What is the medicine intended for?

- Treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH).
- Reduction in the risk of acute urinary retention (AUR) and surgery in patients with moderate to severe symptoms of BPH.

**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.

As the prostate grows, it can lead to urinary system 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 condition 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).

#### Therapeutic group

5-alpha reductase inhibitors.

### 2. Before using the medicine

#### Do not use the medicine if:

- **you are sensitive (allergic) to dutasteride, to other 5-alpha reductase inhibitors, soya, peanuts** or to any of the additional ingredients contained in the medicine as listed in section 6.
- **you have a severe liver disease.**

→ if you think any of these apply to you do not take the medicine and tell your physician.

**The medicine is intended for men only!** This preparation must not be used by women, children or adolescents.

#### Special warnings regarding the use of the medicine

Talk to your physician before taking Avodart.

- **Make sure your physician knows if you have 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 avoid contact with 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 fetus. 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 physician 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 physician 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 physician about these changes as these may be signs of a serious condition, such as breast cancer.

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

#### Drug interactions:

**If you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist. In particular if you are taking** some medicines that 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 - human immunodeficiency virus)
- **itraconazole or ketoconazole** (for fungal infections)
- **nefazodone** (an antidepressant)
- **alpha-blockers** (for enlarged prostate or high blood pressure).

→ **Tell your physician** if you are taking any of these medicines. There may be a need to reduce the Avodart dosage you are taking.

#### Using the medicine and food

Avodart can be taken with or without food.

#### Pregnancy, breast-feeding and fertility

**Women who are pregnant (or may be pregnant) must avoid contact with leaking capsules.** Dutasteride is absorbed through the skin and can affect the normal development of a male fetus. This risk is increased during 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.

→ **Tell your physician** 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 ingredients of the medicine

##### Avodart contains lecithin from soya

This medicine contains lecithin from soya, which may contain soya oil. If you are allergic to peanuts or soya, do not use this medicine.

### 3. How should you use the medicine?

Always use this preparation according to the physician's instructions. Check with the physician or the pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined only by the physician.

#### The recommended dosage is one capsule (0.5 mg) taken once a day.

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 physician tells you.

#### Do not exceed the recommended dose.

Swallow the capsules whole with water. Do not chew and do not open and disperse the contents of the capsule since contact with the contents of the capsule may make your mouth or throat sore.

**If you have accidentally taken an overdose** you should consult your physician or pharmacist.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

**If you forgot to take this medicine** at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult the physician.

Persist with the treatment as recommended by the physician. Even if there is an improvement in your health, do not stop the treatment with the medicine without consulting the physician. It may take 6 or more months before you feel the effect of the medicine.

If you do not take the medicine regularly, the monitoring of your PSA levels may be affected.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

→ **If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.**

### 4. Side effects

As with any medicine, use of Avodart may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of 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.**

→ **Tell your physician immediately** if you get any of these symptoms, and **stop using Avodart.**

Additional side effects

#### Common side effects

*Effects that occur in up to 1 user 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

*Effects that occur in up to 1 user 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.

#### Side effects of unknown frequency

The frequency cannot be estimated from the available data:

- depression
- pain and swelling in your testicles.

→ **If a side effect occurs, if any of the side effects get worse, or when you suffer from side effect not mentioned in the leaflet, you should consult the physician.**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

### 5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the latest day of that month.

Store below 30°C.

### 6. Additional information

- In addition to the active ingredient the medicine also contains: mono and diglycerides of caprylic/capric acid, gelatin, glycerol, titanium dioxide (E171), iron oxide yellow (E172), butylated hydroxytoluene (E321), triglycerides (medium chain), lecithin (may contain soya oil).

- What does the medicine look like and what is the content of the package:

Avodart soft gelatin capsules are opaque, oblong, yellow and marked with GX CE2. They are available in packs of 10, 30, 50, 60 and 90 capsules.

Not all pack sizes may be marketed

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.

- Manufacturer: GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland.

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