

# Avodart<sup>®</sup> 0.5 mg soft capsules

## dutasteride

### Patient information leaflet

This leaflet contains important information about Avodart 0.5mg soft capsules (referred to as Avodart from now on).

It is very important that you read this leaflet carefully before you start taking this medicine to make sure it is right for you.

- Keep this leaflet safe as you may want to read it again.
- If you have any more questions, please ask your doctor or pharmacist.
- Your doctor has prescribed this medicine for YOU. Do not give it to anyone else because it may harm them.

### This leaflet contains the following information about Avodart:

1. What Avodart does
2. Before you take Avodart
3. Taking Avodart with other medicines
4. How to take Avodart
5. If you take too many Avodart capsules
6. If you miss a dose
7. When you should STOP taking Avodart and possible side effects
8. Looking after your Avodart capsules

Each Avodart capsule contains 0.5 mg of the active ingredient, dutasteride.

There are also some inactive ingredients in your medicine. The solution inside the capsule shell contains mono and diglycerides of caprylic/capric acid and butylated hydroxytoluene (E321). The capsule shell contains gelatin, glycerol, titanium dioxide (E171), iron oxide yellow (E172), triglycerides, lecithin and red printing ink containing iron oxide red (E172) as the colourant, polyvinyl acetate phthalate, propylene glycol and macrogol (polyethylene glycol).

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

### Product licence holder and manufacturer

The product licence holder is GlaxoSmithKline UK Limited, Stockley Park West, Uxbridge, Middlesex UB11 1BT. The capsules are made by Cardinal Health France 404, Beinheim, France.

### 1. What Avodart does

Avodart belongs to a group of medicines called 5-alpha reductase inhibitors which are used to treat men who have a condition known as benign prostatic hyperplasia (BPH).

BPH is a condition in which the prostate gland, which is near the bladder, becomes large enough to squeeze the urine tube making it more difficult

for you to pass urine. When this happens you may have some or all of the following symptoms:

- Difficulty in passing urine/water
- An interrupted weak flow of urine
- Frequent passing of urine especially at night
- A feeling that you must urinate (or pass water) straight away
- A feeling that you cannot empty your bladder completely
- If not treated, BPH can lead to an increased risk of complete inability to pass urine (known as acute urinary retention or AUR)
- Leaking and dribbling of urine.

### How Avodart works

Prostate growth is caused by a hormone called dihydrotestosterone (DHT), which is present in blood. Avodart lowers the production of this hormone, leading to reduction in size of the prostate in most men. In order to treat your symptoms and control your BPH effectively, it is important that you continue to take Avodart for as long as your doctor prescribes it, even if you do not feel an immediate benefit. Some patients show early improvements in symptoms, but most men may need to take Avodart for up to 6 months to see if it helps. Avodart works best when taken long term.

### 2. Before you take Avodart

**This medicine is for men only and should not be taken or handled by women, children or adolescents.**

You should NOT take Avodart if you:

- have ever had an allergic reaction (for example, a rash, itching or shortness of breath) to Avodart, dutasteride or any of the other ingredients in Avodart, listed at the beginning of this leaflet or to any other 5-alpha reductase inhibitor.
- have a serious liver disease.

If you have any type of liver disease, even if it is not serious, please discuss this with your doctor before you take Avodart.

The solution from the capsule may be absorbed through the skin, so it is important to thoroughly wash your hands with soap and water if you have handled any capsules which are punctured or leaking.

### Avoiding contact between Avodart and pregnant women

Your semen may contain small amounts of the active ingredient in Avodart which could affect the normal development of a male baby. Therefore, if your partner is or may be pregnant, you must avoid exposing her to your semen, for example by wearing a condom during sex.

If a pregnant woman comes into contact with the active ingredient in Avodart (for example by handling broken capsules or by unprotected sex), please consult a doctor.

### Driving and using machines

Based on how dutasteride works, treatment with dutasteride would not be expected to interfere with the ability to drive or operate machinery.

### Important information about ingredients of Avodart capsules

These capsules contain glycerol, which can in high doses cause headache, stomach upset and diarrhoea. They also contain butylated hydroxytoluene, which can cause irritation to the eyes, skin and mucous membranes if punctured capsules are handled.

## 3. Taking Avodart with other medicines

Avodart does not usually interfere with other medicines. However, you should tell your doctor if you are taking any medication including herbal remedies or dietary supplements you may have bought yourself.

## 4. How to take Avodart

You must take your Avodart capsules in the way your doctor has told you to. The label on your pack should tell you how many capsules to take and how often to take them. If the label doesn't say or if you are not sure, ask your doctor or pharmacist.

- The usual dosage is one capsule (0.5mg) to be taken once a day.
- The capsules should be swallowed whole (do not chew), with water and can be taken with or without food.
- In order to treat your symptoms and control your BPH effectively, it is important that you continue to take Avodart as long as your doctor prescribes it for you, even if you do not feel an immediate benefit. Some patients show early improvement in symptoms, but you may need to take Avodart for up to six months to see if it helps. You must continue to take your medicine as your symptoms improve. Do not stop taking your medicine unless your doctor tells you to stop.

## 5. If you take too many Avodart capsules

If you take too many Avodart capsules, ask your doctor what to do IMMEDIATELY or contact your nearest accident and emergency department.

## 6. If you miss a dose

If you forget to take a dose just carry on with the next one as usual. Do not take any extra capsules to make up for doses you may have forgotten.

## 7. When you should STOP taking Avodart and possible side effects

As with all medicines, some people may have an allergic reaction to Avodart.

STOP taking the medicine and tell your doctor IMMEDIATELY if you experience any of the following severe allergy symptoms after taking Avodart.

- sudden wheezing, tightness of the chest or throat, or difficulty breathing
- swollen eyelids, face, lips, tongue or other part of the body
- lumpy skin rash or 'hives' (like a nettle rash) or blistering of the skin, especially if this is widespread or if you get a sore mouth or eyes, itchiness or fever.

Although they are rare, these symptoms could be serious.

Like any medicine, Avodart can have side effects, however, these are uncommon and do not affect most men.

The following have been reported:

- impotence (not able to achieve or maintain an erection)
- decrease in libido (decreased desire to have sex or a reduced sex drive)
- changes or problems with ejaculation, such as decrease in amount of semen released during sex or a decreased sperm count
- breast swelling or tenderness.

If any of these symptoms occur you do not have to stop taking your medicine but you should seek advice from your doctor.

If you have any other symptoms that you do not understand, tell your pharmacist or doctor.

## 8. Looking after your Avodart capsules

- As with all medicines, it is important to keep Avodart out of the reach and sight of children.
- Do not store Avodart above 30°C. Store the capsules in the original pack.
- Do not use Avodart after the expiry date printed on the carton or the foil blister strip.
- If you have any Avodart capsules left after completing your course of treatment, please return them to your pharmacist who will get rid of them safely.

### Remember

This medicine has been prescribed for YOU. Never give it to women, children, adolescents or other men, as it may harm them even if their symptoms are the same as yours.

### Further information

In addition to taking Avodart capsules, the following changes to your habits may also help improve your urinary symptoms.

- drink less fluid before going to bed
- avoid drinking coffee and/or alcohol

This leaflet does not tell you all about your medicine. If you have any questions or are not sure about anything then ask your doctor or pharmacist.

**This leaflet was revised in: October 2005**

The information in this leaflet only applies to Avodart

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