PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

AVODART Soft Gelatine Capsules

Dutasteride 0,5 mg/capsule

Sugar Free

Read all of this leaflet carefully before you start taking AVODART.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- AVODART has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What AVODART is and what it is used for
2. What you need to know before you take AVODART
3. How to use AVODART
4. Possible side effects
5. How to store AVODART
6. Contents of the pack and other information

1. What AVODART is and what it is used for:

Dutasteride is a 5-alpha-reductase inhibitor.

AVODART is used to treat men with an enlarged prostate (benign prostatic hyperplasia)

2. What you need to know before you take AVODART:

Do not take AVODART:

- if you are allergic (hypersensitive) to dutasteride or any of the other ingredients of AVODART, or to other medicines known as 5-α reductase inhibitors
- if you are a female or under 18 years of age. AVODART is for **adult men only**.

If any of the above apply to you, **don't take AVODART** until you have checked with your doctor.

Warnings and precautions:

Take special care with 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.
- Leaking capsules may cause irritation to your mouth, throat and gullet (oesophagus). Leaking capsules should be discarded. Do not swallow leaking capsules.
- If you have liver disease, check with your doctor that AVODART is suitable for you. You may need extra check-ups while you are taking AVODART.
- In clinical studies with AVODART, some patients took AVODART and a type of medicine called an alpha-blocker (e.g. tamsulosin). The patients taking AVODART and an alpha-blocker had heart failure more often than patients taking only AVODART or only an alpha-blocker. (Heart failure means your heart does not pump blood as well as it should.) If you are taking AVODART and an alpha-blocker, talk to your doctor about this and other possible side effects.

- AVODART can 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**.**
- In a clinical study of men at increased risk of prostate cancer, men taking AVODART had a more serious form of prostate cancer more often than men who did not take AVODART.
- Men taking AVODART should have their PSA measured 6 months after starting treatment and regularly thereafter. Taking AVODART will reduce the amount of PSA measured in your blood. You could still be at risk for prostate cancer even though your PSA is normal.

Other medicine and AVODART:

- Always tell your healthcare professional if you are taking any other medicines. (This includes complementary or traditional medicines.)

AVODART with food and drink:

Avodart can be taken with or without food.

Pregnancy, breastfeeding and fertility:

If you are female, you should not take AVODART.

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 sex. 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.

Contact your doctor for advice if a pregnant woman has come into contact with the contents of a

AVODART capsule.

Male Fertility:

AVODART has been shown to reduce sperm count, semen volume and sperm movement and may reduce fertility.

AVODART has been shown to reduce sex drive.

Driving and using machines:

AVODART can cause dizziness, mainly when taken in combination with an alpha-one blocker. If you are taking AVODART and an alpha-blocker, do not drive or operate machinery unless you are feeling well. If you have any concerns consult your doctor.

3. How to take AVODART:

Do not share medicines prescribed for you with any other person.

Always take AVODART exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one AVODART capsule (0,5 mg) taken once a day.

Swallow your AVODART capsule whole with some water. Do not chew or open the capsule.

Contact with the contents of the capsule may make your mouth, throat or gullet sore.

AVODART is a long-term treatment. Some men may notice an early improvement in their symptoms. However, most may need to continue treatment for up to 6 months to see if AVODART helps them.

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.

If you take more AVODART than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you stop taking AVODART:

Take AVODART for as long as your doctor recommends. 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.

4. Possible side effects:

AVODART can have side effects.

Not all side effects reported for AVODART are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AVODART, please consult your doctor, pharmacist or other healthcare professional for advice.

Some people can be allergic to medicines. If you have any of the following symptoms soon after taking AVODART, STOP taking this medicine and tell your doctor immediately or go to the nearest hospital casualty (accident and emergency) department.

- raised and itchy rash (hives)
- swelling, sometimes of the face or mouth (angioedema) causing difficulty in breathing
- collapse.

These are serious side effects and signs of a severe allergic reaction for which you may need urgent medical attention.

Frequent side effects include:

- impotence (inability to achieve or maintain an erection)
- decrease sex drive (libido)
- difficulty with ejaculation

- breast enlargement or tenderness (gynaecomastia)

Less frequent side effects include:

- dizziness, especially when taken with alpha-one blocker.

Other side effects include:

- depressed mood
- loss of body hair or excess growth of body hair
- pain and swelling of testicles.

If any of these symptoms occur you do not have to stop taking your medicine but tell your doctor when you next visit.

If you notice any side effects not mentioned in this leaflet, tell your doctor or pharmacist

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of AVODART.

5. How to store AVODART:

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not use after the expiry date on the carton.

Return any unused capsules to a pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

WHAT AVODART CONTAINS:

The active ingredient is dutasteride.

Each soft gelatine capsule contains 0,5 mg dutasteride.

Inactive ingredients:

The solution inside the capsule shell contains monodiglycerides of caprylic/capric acid and butylated hydroxytoluene (0,01 % *m/m* as an anti-oxidant).

The capsule shell contains gelatin, glycerol, titanium dioxide, yellow iron oxide, medium chain triglycerides and lecithin as capsule lubricants.

The red printing ink contains iron oxide red as the colourant, polyvinyl acetate phthalate, polyethylene glycol, and propylene glycol.

What AVODART looks like and contents of the pack:

AVODART soft capsules are oblong opaque, dull-yellow, soft gelatine capsules imprinted with GX CE2 on one side in red ink.

Opaque, PVC/PVdC film-containing blisters of 10 soft gelatin capsules, packed into cartons of 30 and 90 capsules.

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

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