

AVODART®

(Dutasteride)

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take AVODART.

This leaflet answers some common questions about AVODART. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking AVODART against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is AVODART used for?

AVODART (dutasteride) belongs to a group of medicines called 5 alpha reductase enzyme inhibitors which are used in men who have a condition known as benign prostatic hyperplasia (BPH).

BPH is a non-cancerous enlargement of the prostate gland which is located at the lower portion of the urinary bladder surrounding the urethra (urine carrying tube). In men with BPH, the prostate gland becomes large enough to squeeze the urine tube running through it. If the urine tube is squeezed it narrows, making it more difficult for you to pass urine normally and you may have some or all of the following symptoms:

- difficulty in starting to urinate
- an interrupted, weak urinary stream
- more frequent urination, especially at night
- feeling that you need to urinate right away
- leaking or dribbling
- a feeling that you cannot empty your bladder completely

As the disease progresses, untreated BPH can lead to an increased risk of complete blockage of urine flow (acute urinary retention) and/or the need for surgery.

Prostate growth is caused by a hormone in the blood called dihydrotestosterone (DHT). AVODART lowers DHT

production in the body, leading to shrinkage of the enlarged prostate in most men. Just as your prostate became large over a long period of time, reducing the size of your prostate and improving your symptoms may take time.

AVODART may also be taken in combination with another type of medicine called an alpha blocker in order to treat symptoms of an enlarged prostate.

AVODART capsules contain the active ingredient dutasteride dissolved in a liquid.

Your doctor may have prescribed AVODART for another reason. Ask your doctor if you are unsure why AVODART was prescribed for you.

AVODART is not addictive.

Before you take AVODART

Do not take if:

You must not take AVODART if:

- you have ever had an allergic reaction to dutasteride, other 5 alpha reductase enzyme inhibitors or any of the ingredients listed toward the end of this leaflet. (See "What are the side effects" and "Ingredients").
- you are a woman or child.
- **the expiry date (EXP) printed on the pack has passed.**

- **the packaging is torn or shows signs of tampering.**

Tell your doctor if:

You must tell your doctor if:

- **you are allergic to foods, dyes, preservatives or any other medicines.**
- **you suffer from liver disease and/or other medical conditions.**
- **you are taking any other medicines, including medicines you buy without a prescription.**

Women (who are pregnant or may be pregnant) and children must avoid handling punctured or leaking capsules. Wash the affected area immediately with soap and water if there is any contact with the skin.

If dutasteride is absorbed through the skin by a woman who is pregnant with a male baby, it may cause the male baby to be born with abnormalities of the genital organs.

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. You must use a condom during sex.

You must not donate blood until 6 months after you've stopped taking AVODART.

How do I take AVODART?

How much to take

Take AVODART as directed by your doctor or pharmacist.

The usual dose in men is one capsule daily.

How to take it

Take AVODART with or without food. Each capsule must be swallowed whole and not chewed or opened. Contact with the contents of the capsule may make your mouth or throat sore.

How long to take it for

It is important to continue to take AVODART for as long as your doctor prescribes it, even if you do not feel any immediate benefit. Some men notice an early improvement in their symptoms, however others may need to continue for 3-6 months to see if AVODART helps them. You must also continue to take your medicine as your symptoms improve.

Do not stop taking AVODART, or change the dose without first checking with your doctor.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or

anyone else may have taken too much AVODART, even if there are no signs of discomfort or poisoning.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking AVODART

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

If you forget to take a capsule, don't worry, just take the next dose as normal and continue as before.

Do not take a double dose to make up for the one you have missed.

AVODART decreases your PSA (prostate-specific antigen) levels. Therefore, if you are having a blood test to measure your PSA levels, tell your doctor you are taking AVODART.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use AVODART to treat any other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how AVODART affects you.

AVODART generally does not cause any problems with your ability to drive a car or operate machinery.

AVODART may also be taken in combination with another type of medicine called an alpha blocker in order to treat symptoms of an enlarged prostate. If you are having a cataract operation and are already taking or have taken an alpha blocker medicine, the pupil may dilate poorly and the iris (the coloured part of the eye) may become floppy during the operation (floppy iris syndrome). This can be managed if your surgeon knows beforehand that you have taken the alpha blocker. If you are going to have eye surgery for cataracts, please tell your surgeon that you are taking or have taken an alpha blocker.

Read the leaflet for the alpha blocker medicine too.

In clinical studies with AVODART, the patients taking AVODART and an alpha-blocker (for example tamsulosin) 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.

In a clinical study of men at increased risk of developing prostate cancer, a serious form of prostate cancer was reported

more often in men taking AVODART than in men who did not take AVODART. The reasons for this is currently unknown but may be due to the design of the clinical study.

A blood test to measure the amount of a substance called PSA (prostate specific antigen) in your blood can help your doctor to tell if you have prostate disease, including prostate cancer. If you have a higher than normal amount of PSA in your blood it could mean that you are at a higher risk of prostate cancer.

Men taking AVODART should have their PSA measured 6 months after starting treatment and then regularly after that. 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 lower. Your doctor can still use PSA to help detect prostate cancer, by comparing your test results each time you have a PSA test.

It is important to take your medicine as your doctor recommends. If you do not take it regularly it may interfere with your doctor's ability to monitor your PSA.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking AVODART, even if the problem is not listed below.

Like other medicines, AVODART can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- impotence (inability to achieve or maintain an erection).
- decrease in libido (sex drive).
- difficulty with ejaculation.
- breast swelling or 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 a breast cancer.
- dizziness when taken with an alpha blocker.

Rarely, the following side effects have been reported:

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

Very rarely, the following side effects have been reported:

- depressed mood
- testicular pain and testicular swelling

You may also experience a decrease in sperm count and semen volume.

Tell your doctor immediately if you notice any of the following:

- **Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.**

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

How do I store AVODART?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Keep AVODART in a cool, dry place where it stays below 30°C.

Do not leave in car, on window sill or in bathroom.

Keep AVODART in its blister pack until it is time to take your dose.

Return any unused or expired medicine to your pharmacist.

Product description

What AVODART looks like

AVODART capsules are oblong, opaque, yellow, soft gelatin capsules marked with GX CE2. AVODART capsules are supplied in blister packs of 10 (sample pack), 30 and 90 capsules.

Not all pack sizes may be distributed in Australia.

Ingredients

AVODART capsules contain the active ingredient:

- dutasteride 500 mcg dissolved in a liquid.

AVODART capsules also contain the inactive ingredients:

- mono- and di- glycerides
- butylated hydroxytoluene

The capsule shells are made of:

- gelatin
- glycerol
- titanium dioxide (CI 77891)
- iron oxide yellow (CI 77492)

Supplier

Your AVODART is supplied by:

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street

Abbotsford Victoria 3067

Australia.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from patient information groups and books, for example in public libraries.

This leaflet was prepared on 01 May 2013.

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AVODART: AUST R 90434

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Version 9.0