

AVORNA 0.5 MG SOFT CAPSULE

Dutasteride (0.5 mg)

What is in this leaflet

1. What AVORNA is used for
2. How AVORNA works
3. Before you use AVORNA
4. How to use AVORNA
5. While you are using it
6. Side Effects
7. Storage and Disposal of AVORNA
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What AVORNA is used for

AVORNA 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 DHT (*dihydrotestosterone*).

How AVORNA works

The active ingredient is dutasteride. It belongs to a group of medicines called 5-alpha reductase inhibitors.

As the prostate grows, it can lead to urinary problems, such as difficulty in passing urine and a need to go to the toilet more frequently. It can also cause the flow of urine to be slower and less forceful. If left untreated, there is a risk that your urine flow will be completely blocked.

AVORNA helps to shrink the prostate and relieve symptoms, by reducing the amount of DHT your body produces.

Before you use AVORNA

- When you must not use it

- if you are allergic (hypersensitive) to dutasteride or to any of the other ingredients of AVORNA, or to other similar medicines known as 5-alpha reductase inhibitors.
- if you are female, children and adolescents. This medicine is for adult men only.
- if you have severe liver impairment.
- if you are allergic to peanut or soya. This product contains lecithin derived from soya oil.

If any of these apply to you, do not take AVORNA until you have checked with your doctor.

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.

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

- Before you start to use it

If you have liver disease, check with your doctor that AVORNA is suitable for you. You may need extra check-ups while you are taking AVORNA.

- Taking other medicines

Based on the available clinical studies with AVORNA, some patients took AVORNA and a type of medicine called an alpha-blocker (for example tamsulosin). The patients taking AVORNA and an alpha-blocker had heart failure more often than patients taking only AVORNA or only an alpha-blocker. (Heart failure means your heart does not pump blood as well as it should.)

If you are taking AVORNA and an alpha-blocker, talk to your doctor about this and other possible side effects.

Tell your doctor if you are taking any other medicines, or have recently taken any. This includes medicines bought without a prescription.

How to use AVORNA

- How much to use

Always take AVORNA 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 capsule (0.5 mg) taken once a day.

- How to take

Swallow your AVORNA capsules whole with some water. Do not chew or open the capsules. Contact with the contents of the capsules may make your mouth or throat sore.

- When to use it

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

- How long to use it

Take AVORNA for as long as your doctor recommends. Do not stop taking AVORNA without talking to your doctor first.

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

- If you forget to use it

Do not take extra capsules to make up for a missed dose. Just take your next dose at the usual time.

- If you use too much (overdose)

If you take too many AVORNA capsules, contact your doctor or pharmacist for advice. If possible, show them the AVORNA pack.

While you are using it

- Things you must do

In a clinical study of men at increased risk of prostate cancer, men taking AVORNA had a serious form of prostate cancer more often than men who did not take AVORNA.

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 AVORNA should have their PSA measured 6 months after starting treatment and regularly thereafter. Taking AVORNA 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.

- Things you must not do

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Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Blood Donation: Men being treated with dutasteride should not donate blood until at least 6 months have passed following their last dose. The purpose of this deferred period is to prevent administration of dutasteride to a pregnant female transfusion recipient.

- Things to be careful of

AVORNA has been shown to reduce sperm count, semen volume and sperm movement.

However, it is not clear if male fertility is affected by AVORNA.

Women, children and adolescents must not handle leaking AVORNA 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.

AVORNA may 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.

Dutasteride would not be expected to interfere with the ability to drive or operate machinery.

Side Effects

Like all medicines, AVORNA can cause side effects, but not everybody gets them.

Conditions you need to look out for

Allergic reaction: These may affect up to 1 in 10,000 people.

Signs can include:

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

Contact a doctor immediately if you get any of these symptoms. Stop taking AVORNA.

Common side effects

These may affect up to 1 in 10 people:

- not able to achieve or maintain an erection (impotence)*
- decreased sex drive
- difficulty with ejaculation*
- breast enlargement or tenderness
- dizziness when taken with tamsulosin.

*In a small number of people some of these events may continue after they stop taking AVORNA

Rare side effects

These may affect up to 1 in 1,000 people:

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

Very rare side effects

The may affect up to 1 in 10,000 people:

- depressed mood
- pain and swelling in your testicles

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my (Consumers → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of AVORNA

- Storage

Keep out of the reach and sight of children.

Do not use AVORNA after the expiry date shown on the pack.

Do not store above 30°C.

Store in the original package in order to protect from light and moisture.

- Disposal

If you have any unwanted AVORNA capsules, do not dispose of them in your waste water or household rubbish. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

Product Description

- What it looks like

AVORNA capsules are oblong, opaque and yellow soft gelatin capsule containing an oily and yellowish liquid.

- Ingredients

- Active ingredient(s)

Each capsule contains 0.5 mg Dutasteride

- Inactive ingredient(s)

Capsule contents: Glycerol Monocaprylocaprate; Butylhydroxytoluene;

Capsule shell:

Gelatin; Glycerol; Titanium Dioxide (E-171); Yellow Iron Oxide (E-172); Medium Chain Triglycerides and Lecithin (may contain soya oil)

- MAL number

MAL25016028ACZ

Manufacturer

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Product Registration Holder

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