AVORNA-DUO 0.5MG/0.4MG HARD CAPSULES

Dutasteride/ tamsulosin hydrochloride (0.5mg/0.4mg)

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What AVORNA-DUO is used for

AVORNA-DUO is used to treat men with moderate to severe symptoms of benign prostatic hyperplasia (BPH) - a non-cancerous growth of the prostate gland caused by producing too much of a hormone called DHT (dihydrotestosterone).

AVORNA-DUO reduces the risk of acute urinary retention and the need for surgery in people with moderate to severe symptoms of BPH.

How AVORNA-DUO works

AVORNA-DUO capsules are a combination of two different medicines called dutasteride and tamsulosin. Dutasteride belongs to a group of medicines called 5-alpha reductase inhibitors, and tamsulosin belongs to a group of medicines called alpha-blockers.

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 the urine to be slower and less forceful. If left untreated, there is a risk that your urine flow will be completely blocked. Dutasteride helps to shrink the prostate and relieve symptoms, by reducing the amount of DHT your body produces. Tamsulosin acts by relaxing the muscles in your prostate gland, making it easier to pass urine, and improving your symptoms.

Before you use AVORNA-DUO

- When you must not use it

Don't take AVORNA-DUO

- if you are allergic (hypersensitive) to dutasteride, tamsulosin or to any of the other ingredients of AVORNA-DUO, or to other medicines known as 5-alpha reductase inhibitors.
- if you are female or age 21 years and below. This medicine is for adult men only.

If any of these apply to you, don't take AVORNA-DUO until you have checked with your doctor.

AVORNA-DUO must also not be taken by individuals with low blood pressure associated with feelings of dizziness upon getting up or standing (orthostatic hypotension), or by individuals with severe liver impairment.

- Before you start to use it

Take special care with AVORNA-DUO

- In clinical studies with dutasteride, some individuals taking dutasteride and an alpha-blocker had heart failure more often than individuals taking only dutasteride or only an alpha-blocker. (Heart failure means your heart does not pump blood as well as it should.) Caution is advised in individuals with coronary heart disease and swallowing disorder.
- If you have mild to moderate liver disease,
- check with your doctor that AVORNA-DUO is suitable for you. You may need extra check-ups while you are taking AVORNA-DUO.
- If you have severe kidney impairment, incomplete bladder emptying and/or severely impaired urine flow.
- If you are going to have cataract (cloudy lens), glaucoma (increased eye pressure) surgery. Tell your doctor or eye specialist before your operation that you are taking, or have previously taken AVORNA-DUO. They may ask you to temporarily stop taking AVORNA-DUO 1-2 weeks before your operation.
- Women, children and adolescents must not handle leaking AVORNA-DUO 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-DUO 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.

- Taking other medicines

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

Don't take AVORNA-DUO with these medicines:

- Other alpha blockers (for enlarged prostate or high blood pressure)

AVORNA-DUO is not recommended with these medicines:

- ketoconazole, itraconazole, fluconazole (used to treat fungal infections)

Some medicines can interact with AVORNA-DUO and may make it more likely that you'll have side-effects. These medicines include:

- PDE5 inhibitors (used to help achieve or maintain an erection).
- warfarin (to prevent blood clotting)
- erythromycin, clarithromycin (antibiotics used to treat infections)
- verapamil, diltiazem, amiodarone (to treat irregular heart beat)
- cimetidine (to treat heartburn)
- paroxetine (an antidepressant)

►This is not a complete list of interactions. Tell your doctor or pharmacist if you are taking any medicines.

How to use AVORNA-DUO

Always take AVORNA-DUO exactly as your doctor has told you. Check with your doctor or pharmacist if you're not sure.

- How much to use

The usual dose of AVORNA-DUO is one capsule (containing 0.5mg dutasteride/0.4mg tamsulosin hydrochloride) taken once a day.

- When to use it

Swallow your AVORNA-DUO capsules whole with some water, approximately 30 minutes after the same meal each day. Don't chew or open the capsules. Contact with the contents of the capsules may make your mouth or throat sore.

- How long to use it

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Take AVORNA-DUO for as long as your doctor recommends. Don't stop taking AVORNA-DUO without talking to your doctor first.

On discontinuing AVORNA-DUO the prostate can go back to the size it was prior to the treatment.

- If you forget to use it
Don't 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-DUO capsules, contact your doctor or pharmacist for advice. If possible, show them the AVORNA-DUO pack. Acute low blood pressure (systolic blood pressure 70 mmHg), vomiting and diarrhea were observed in these people.

While you are using it
- Things you must do
- Based on available study of men at increased risk of prostate cancer, men taking dutasteride had a serious form of prostate cancer more often than men who did not take dutasteride.
- 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 have prostate cancer.
- Men taking AVORNA-DUO should have their PSA measured 6 months after starting treatment and regularly thereafter. Taking AVORNA-DUO 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
This medicine has been prescribed for you personally. Don't pass it on to other people - it may harm them even if their symptoms seem to be the same as yours.

- Things to be careful of

Pregnancy and breast-feeding
- 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 a AVORNA-DUO capsule.

Male Fertility
AVORNA-DUO has been shown to reduce sperm count, semen volume and sperm movement. However, it is not clear if male fertility is affected by AVORNA-DUO.

Driving and using machines
AVORNA-DUO can make some people feel dizzy and have vision disturbance. Don't drive or operate machinery unless you're feeling well.

Side Effects
Like all medicines, AVORNA-DUO can cause side effects, but not everybody gets them.

Dizziness, light-headedness and fainting: AVORNA-DUO can cause dizziness, light-headedness and on rare occasions fainting. Take care when moving from a lying down or sitting position to sitting or standing, particularly if you wake up in the night, until you know how this medicine affects you. If you feel dizzy or light-headed at any time during treatment, sit or lie down until the symptoms pass.

Allergic reactions: 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-DUO.

Serious skin reactions: These may affect for people taking AVORNA-DUO. Signs can include:
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).

Contact a doctor immediately if you get these symptoms. Stop taking AVORNA-DUO.

Common side effects
- not able to achieve or maintain an erection
- decreased sex drive*
- difficulty with ejaculation*
- breast enlargement or tenderness

* these events may continue after you stop taking AVORNA-DUO.

Uncommon side effects
- feeling of fast heart beat
- constipation, diarrhoea, vomiting, nausea
- weakness or loss of strength
- itchy, blocked or runny nose

Very rare side effects
- persistent painful erection of the penis

Contact a doctor urgently if this happens to you. You may need to have treatment to avoid serious complications.
- depressed mood
- pain and swelling in your testicles.

Other side effects
Other side effects have occurred but their exact frequency is unknown:
- irregular or fast heartbeat
- shortness of breath
- breast cancer in men

If you get side effects
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 npra.gov.my [Customer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

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Storage and Disposal of AVORNA-DUO

- Storage

- Keep out of the reach and sight of children.
- Do not take AVORNA-DUO after the expiry date shown on the pack.
- Store below 30°C. Protect from light and moisture.

- Disposal

If you have any unwanted AVORNA-DUO capsules, don't 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

Hard capsules. Orange cap and brown body hard capsules containing white to off-white one yellow soft gelatin capsule with an oily and yellowish liquid.

Packs:
- 3 x 10 Capsules
- 5 x 6 Capsules

- Ingredients

- Active ingredient(s)
Dutasteride, tamsulosin hydrochloride

- Inactive ingredient(s)
Glycerol monocaprylocaprate, butylhydroxytoluene, gelatin, glycerol, titanium dioxide, yellow iron oxide, purified water, triglycerides, medium chain, lecithin, microcrystalline cellulose, magnesium strearate, methacrylic acid-ethyl acrylate copolymer (1:1), sodium hydroxide, triacetin, purified talc, and talc.

- MAL number

MAL24116029ACZ

Manufacturer

SAG MANUFACTURING, S.L.U
Carretera Nacional 1 Km 36, San Agustin del Guadalix 28750
Madrid – Spain.

Product Registration Holder

Pharmaniaga Marketing Sdn Bhd (198401005734)
No. 7, Lorong Kelulli 1B,
Kawasan Perindustrian Bukit Raja Selatan, Seksyen 7, 40000 Shah Alam,
Selangor Darul Ehsan.

Date of Revision

30/04/2026

Serial Number

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