ADUTASIN HARD CAPSULE

Dutasteride/Tamsulosin Hydrochloride (0.5mg/0.4mg)

What is in this leaflet

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

What ADUTASIN is used for

ADUTASIN 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).

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

How ADUTASIN works

ADUTASIN 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 ADUTASIN

- *When you must not use it*

  Do not take ADUTASIN:
  - if you are allergic (hypersensitive) to dutasteride, tamsulosin or to any of the other ingredients of ADUTASIN, 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 ADUTASIN until you have checked with your doctor.

  ADUTASIN 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.

  Pregnancy and lactation

  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.

  Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

- *Before you start to use it*

  Take special care with ADUTASIN
  - 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 ADUTASIN is suitable for you. You may need extra check-ups while you are taking ADUTASIN.
  - 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 ADUTASIN. They may ask you to temporarily stop taking ADUTASIN 1-2 weeks before your operation.
  - Women, children and adolescents must not handle leaking ADUTASIN 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.
  - ADUTASIN 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 ADUTASIN with these medicines:
  - other alpha blockers (for enlarged prostate or high blood pressure)

  ADUTASIN is not recommended with these medicines:
  - ketoconazole, itraconazole, fluconazole (used to treat fungal infections)

  Some medicines can interact with ADUTASIN 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 heartbeat)
  - 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 ADUTASIN

Always take ADUTASIN exactly as your doctor has told you. Check with

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your doctor or pharmacist if you're not sure.

- *How much to use*
  The usual dose of ADUTASIN is one capsule (containing 0.5 mg dutasteride/ 0.4 mg tamsulosin) taken once a day.

- *When to use it*
  Swallow your ADUTASIN 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*
  Take ADUTASIN for as long as your doctor recommends. Don't stop taking ADUTASIN without talking to your doctor first.

  On discontinuing ADUTASIN 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 ADUTASIN capsules, contact your doctor or pharmacist for advice. If possible, show them the ADUTASIN pack. Acute low blood pressure (systolic blood pressure 70 mmHg), vomiting and diarrhea were observed in these people.

While you are using ADUTASIN

- *Things you must do*
  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 ADUTASIN should have their PSA measured 6 months after starting treatment and regularly thereafter.

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

  Driving and using machines
  ADUTASIN 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, ADUTASIN can cause side effects, but not everybody gets them.

Dizziness, light-headedness and fainting:
ADUTASIN 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 ADUTASIN.

Serious skin reactions:
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 ADUTASIN.

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 ADUTASIN.

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.

ADUTASIN HARD CAPSULE

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

Storage and Disposal of ADUTASIN

- *Storage*
  Keep out of reach of children.
  Do not store above 30°C.
  Store in the original container to protect from moisture.

- *Disposal*
  Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*
  Orange cap and brown body hard capsules containing white to off white pellets and one yellow soft gelatin capsule with an oily and yellowish liquid.

- *Ingredients*
  - Active ingredient:
    Dutasteride and Tamsulosin Hydrochloride

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

- *MAL number:*
  MAL*********

Manufacturer
SAG Manufacturing, S.L.U.
Carretera Nacional 1 Km 36,
San Agustín del Guadalix,
28750 Madrid, Spain.

Product Registration Holder
Apex Pharmacy Marketing Sdn Bhd
No. 2, Jalan SS 13/5,
47500 Subang Jaya,
Selangor, Malaysia.

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23/04/2026

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