

DUTABIT PLUS CAPSULES

Dutasteride/Tamsulosin Hydrochloride (0.5mg/0.4mg)

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What is Dutabit Plus used for

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

How Dutabit Plus works

Dutabit Plus 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 Dutabit Plus

-When you must not use it

Do not take Dutabit Plus:

- if you are allergic (hypersensitive) to dutasteride, tamsulosin or to any of the other ingredients of Dutabit Plus, 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 Dutabit Plus until you have checked with your doctor.

Dutabit Plus 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 Dutabit Plus

- 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 Dutabit Plus is suitable for you. You may need extra check-ups while you are taking Dutabit Plus.
- 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 Dutabit Plus. They may ask you to temporarily stop

taking Dutabit Plus 1-2 weeks before your operation.

- Women, children and adolescents must not handle leaking Dutabit Plus 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.
- Dutabit Plus 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 medications

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 Dutabit Plus with these medicines:

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

Dutabit Plus is not recommended with these medicines:

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

Some medicines can interact with Dutabit Plus 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.

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How to use Dutabit Plus

Always take Dutabit Plus 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 Dutabit Plus is one capsule (containing 0.5 mg dutasteride/0.4 mg tamsulosin) taken once a day.

-When to use it

Swallow your Dutabit Plus 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 Dutabit Plus for as long as your doctor recommends. Don't stop taking Dutabit Plus without talking to your doctor first.

On discontinuing Dutabit Plus 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 Dutabit Plus capsules, contact your doctor or pharmacist for advice. If possible, show them the Dutabit Plus 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

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 Dutabit Plus should have their PSA measured 6 months after starting treatment and regularly thereafter.

Taking Dutabit Plus 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 Dutabit Plus capsule.

Male Fertility

Dutabit Plus has been shown to reduce sperm count, semen volume and sperm movement. However, it is not clear if male fertility is affected by Dutabit Plus.

Driving and using machines

Dutabit Plus 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, Dutabit Plus can cause side effects, but not everybody gets them.

Dizziness, light-headedness and fainting: Dutabit Plus 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 Dutabit Plus.

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 Dutabit Plus.

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 Dutabit Plus.

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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 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 Dutabit Plus

-Storage

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the label after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

-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

Dutabit Plus is Size '00', hard shell capsules having opaque orange cap imprinted with 'DTT' in black ink and opaque brown body imprinted with '0.5/0.4' in black ink containing one dutasteride soft gelatin capsule and white to off white Tamsulosin Hydrochloride beadlets.

-Ingredients

- Active ingredient(s)
The active substances are Dutasteride and Tamsulosin Hydrochloride. Each capsule contains 0.5 mg of dutasteride and 0.4 mg of Tamsulosin Hydrochloride.
- Inactive ingredient(s)
- Contents in Dutasteride soft capsules:
- Glycerol monooctadecanoate (Type-I), Butylhydroxytoluene (E321).
- Soft capsule shell: Gelatin (160 bloom), Glycerol, Titanium dioxide (E171), Iron oxide yellow (E172)
- Contents in Tamsulosin Hydrochloride Beadlets
- Cellulose, Microcrystalline (Grade-101), Talc, Methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 percent (contains 0.7% Sodium Laurylsulfate and 2.3% Polysorbate 80), Triacetin, Calcium Stearate.
- Hard capsule shell: Hypromellose, Carrageenan, Potassium chloride, Titanium dioxide (E171), Iron oxide black (E172), Iron oxide red (E172),

Sunset yellow FCF (FD&C Yellow 6) (E 110).

- Printing ink (Black): Shellac (E904), Black iron oxide (E172), Potassium hydroxide.

-MAL number

MALXXXXXXXXXX

Manufacturer

Aurobindo Pharma Limited,

Unit VII, Special Economic Zone Tsiic, Plot No S1, Sy Nos 411/P 425/P 434/P 435/P And 458/P Green Industrial Park, Jadcherla Mandal, Mahabubnagar District, Polepally Village, 509302, India

Product Registration Holder

HEALOL PHARMACEUTICALS SDN BHD.

No. 74-3, Jalan Wangsa Delima 6, KLSC Wangsa Maju, 53300 Kuala Lumpur, Malaysia.

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