

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed according to a doctor's prescription only

Dutasterided Hard Capsules

Each capsule contains 0.5 mg dutasteride and 0.4 mg tamsulosin hydrochloride.

For a list of the inactive and allergenic ingredients, see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is intended for men only.

1. WHAT IS THE MEDICINE INTENDED FOR?

- Treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH).
- Reduction in the risk of acute urinary retention (AUR) and surgery in patients with moderate to severe symptoms of BPH.

Dutasterided 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 dihydrotestosterone.

Growth of the prostate can lead to urinary problems, such as difficulty in passing urine and a need to go to the toilet frequently. It can also cause the flow of the urine to be slower and weaker. If left untreated, there is a risk that your urine flow will be completely blocked (acute urinary retention). This situation requires immediate medical treatment. Sometimes surgery is necessary to remove or reduce the size of the prostate gland.

Dutasterided lowers the production of the hormone called dihydrotestosterone, which helps to shrink the prostate and relieve the symptoms. This will reduce the risk of acute urinary retention and the need for surgery. Tamsulosin acts by relaxing the muscles in the prostate gland, making it easier to pass urine and rapidly improving your symptoms.

Therapeutic group: Dutasterided is a combination of two different medicines called dutasteride and tamsulosin. Dutasterided belongs to a group of medicines called 5-alpha reductase inhibitors and tamsulosin belongs to a group of medicines called alpha-blockers.

2. BEFORE USING THE MEDICINE

Do not use Dutasterided:

- **if you are sensitive (allergic) to the active ingredients dutasteride and tamsulosin hydrochloride, to other 5-alpha reductase inhibitors** or to any of the additional ingredients contained in the medicine as detailed in section 6.
 - **in women** (as the medicine is intended for men only).
 - **in children or adolescents under the age of 18.**
 - **if you have low blood pressure** which makes you feel dizzy, lightheaded or faint (orthostatic hypotension).
 - **if you have severe liver disease.**
- If you think any of these apply to you, do not take the medicine and tell your doctor.

Special warnings regarding the use of the medicine Talk to your doctor before you take Dutasterided.

- In some clinical studies, more patients taking dutasteride and another medicine called an alpha-blocker, like tamsulosin, experienced heart failure than patients taking only dutasteride or only an alpha-blocker. Heart failure means your heart does not pump blood as well as it should.
- **Make sure your doctor knows if you have liver problems.** If you have had any illness that affected your liver, you may need some additional check-ups while you are taking Dutasterided.
- **Make sure your doctor knows if you have severe kidney problems.**
- **Cataract (opacity of the lens of the eye) surgery.** If you are going to have surgery to remove a cataract, your doctor may ask you to stop taking Dutasterided for a while before your operation. Tell your ophthalmologist before your operation that you are taking Dutasterided or tamsulosin (or have taken these medicines in the past). Your ophthalmologist will need to take appropriate precautions to help prevent complications during your operation.
- **Women, children and adolescents** must avoid contact with leaking Dutasterided 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.

- **Use a condom during sexual intercourse.** Dutasterided has been found in the semen of men taking Dutasterided. 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 fetus. Dutasterided has been found to decrease sperm count, semen volume and sperm motility. This could reduce your fertility.

- **Dutasterided affects a blood test for PSA** (*prostate-specific antigen*), which is sometimes used to detect prostate cancer. Your doctor should be aware of this effect and can still use this test to detect prostate cancer. If you are having a blood test for PSA, tell your doctor that you are taking Dutasterided. **Men taking Dutasterided should have their PSA tested regularly.**

- In a clinical study of men at increased risk of prostate cancer, men who took dutasteride developed a **severe form of prostate cancer more often** than men who did not take dutasteride. The effect of dutasteride on this serious form of prostate cancer is not clear.

- **Dutasterided 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 medical condition, such as breast cancer.

→**Contact your doctor or pharmacist** if you have any questions about taking Dutasterided.

Children and adolescents

Do not use Dutasterided in children and adolescents under the age of 18.

Drug interactions:

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.

Do not take Dutasterided with the following medicines:

- **other alpha-blockers** (for treatment of enlarged prostate or high blood pressure)
- Dutasterided is not recommended with the following medicines:
- **ketoconazole** (used to treat fungal infections)
- Some medicines can react with Dutasterided, which may make it more likely that you will have side effects. These medicines include:
- **PDE5 inhibitors** (used to achieve or maintain an erection) such as: vardenafil, sildenafil citrate and tadalafil
 - **verapamil or diltiazem** (for high blood pressure)
 - **ritonavir or indinavir** (for HIV – human immunodeficiency virus)
 - **itraconazole or ketoconazole** (for fungal infections)
 - **nefazodone** (an antidepressant)
 - **cimetidine** (for stomach ulcer)
 - **warfarin** (for blood clotting)
 - **erythromycin** (an antibiotic used to treat infections)
 - **paroxetine** (an antidepressant)
 - **terbinafine** (used to treat fungal infections)
 - **diclofenac** (used to treat pain and inflammation)

→**Tell your doctor** if you are taking any of these medicines.

Using the medicine and food

Take Dutasterided 30 minutes after the same meal each day.

Pregnancy, breast-feeding and fertility

Dutasterided is prohibited for use in women.

Pregnancy

Women who are pregnant (or may be pregnant) must avoid contact with leaking capsules.

Dutasterided is absorbed through the skin and may affect the normal development of a male fetus. This risk is increased during the first 16 weeks of pregnancy.

Use a condom during sexual intercourse. Dutasterided has been found in the semen of men taking Dutasterided. If your partner is or may be pregnant, you must avoid exposing her to your semen.

→**Tell your doctor** if a pregnant woman has come into contact with Dutasterided.

Fertility

Dutasterided has been found to reduce sperm count, semen volume and sperm movement. Therefore, male fertility may be reduced.

Driving and using machines

Dutasterided may cause dizziness in some people, so it may affect your ability to drive or operate machinery safely. →**Do not drive or operate machinery** if you experience this effect.

Important information about some of the ingredients of the medicine

Dutasterided contains the coloring agent Sunset yellow (E110), which is also called FD&C yellow 6, which may cause an allergic reaction.

Dutasterided contains less than 23 mg sodium per capsule and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or the pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally one capsule taken once a day, 30 minutes after the same meal each day.

Do not exceed the recommended dose.

Swallow the capsule whole with water. Do not chew and do not open and disperse the contents of the capsule since contact with the contents of the capsule may make your mouth or throat sore.

If you have accidentally taken a higher dose, you should consult your doctor or pharmacist.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the designated time, do not take a double dose. Take the next dose at the usual time and consult the doctor.

Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop the treatment with the medicine without consulting the doctor.

If you do not take the medicine regularly, the monitoring of your PSA levels may be affected.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Dutasterided may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Allergic reaction

The symptoms of an allergic reaction can include:

- **skin rash** (which can be itchy)
- **hives** (like a nettle rash)
- **swelling of the eyelids, face, lips, arms or legs**

→**Tell your doctor immediately** if you notice any of these symptoms, and **stop using Dutasterided.**

Dizziness, lightheadedness and fainting

Dutasterided can cause dizziness, lightheadedness and on rare occasions, fainting.

Take care when moving from a lying down or sitting position to a sitting or standing position, particularly if you wake up during the night, until you know how this medicine affects you. If you feel dizzy or lightheaded at any time during treatment, **sit or lie down until the symptoms pass.**

Serious skin reactions

The signs of serious skin reactions can include:

- **a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals** (Stevens-Johnson syndrome)

→**Contact your doctor immediately** if you notice any of these symptoms and **stop using Dutasterided.**

Additional side effects

Common side effects – effects occurring in 1-10 in 100 men taking Dutasterided:

- impotence (inability to achieve or maintain an erection)*
- decreased sex drive (libido)*
- ejaculation disturbances, such as a decrease in the amount of semen released during sex*
- tenderness or enlargement of the breast (gynecomastia)
- dizziness

* In a small number of people, some of these events may continue after discontinuation of Dutasterided.

Uncommon side effects – effects occurring in 1-10 in 1,000 men taking Dutasterided:

- heart failure (heart becomes less efficient at pumping blood around the body. You may have symptoms such as shortness of breath, extreme tiredness and swelling in your ankles and legs)
- low blood pressure on standing
- fast heartbeat (palpitations)
- constipation, diarrhea, vomiting, nausea
- weakness or loss of strength
- headache
- itchy, blocked or runny nose (rhinitis)
- skin rash, hives, itching
- hair loss (usually from the body) or hair growth

Rare side effects – effects occurring in 1-10 in 10,000 men taking Dutasterided:

- swelling of the eyelids, face, lips, arms or legs (angioedema)
- fainting

Very rare side effects – effects occurring in less than one in 10,000 men taking Dutasterided:

- persistent and painful erection
- serious skin reactions (Stevens-Johnson syndrome)

Side effects of unknown frequency (effects whose frequency has not yet been determined)

Other side effects have occurred in a small number of men, but their frequency is not known (the frequency cannot be estimated from available data):

- abnormal or fast heartbeat (arrhythmia or tachycardia or atrial fibrillation)
- shortness of breath
- depression
- pain and swelling in the testicles
- nosebleed
- severe skin rash
- vision changes (blurred vision or impaired vision)
- dry mouth

→**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- The bottle package should be stored below 25°C. The tray package should be stored below 30°C. Bottle package – the shelf life after first opening the bottle containing 30 hard capsules – can be used for two years, but no later than the preparation expiry date.

6. FURTHER INFORMATION

- **In addition to the active ingredients, the medicine also contains:**

- Composition of hard capsule shell: In Cap: Hypromellose, carrageenan, potassium chloride, titanium dioxide (E171), sunset yellow FCF (FD&C yellow 6) (E110) and iron oxide red (E172). In Body: Hypromellose, carrageenan, potassium chloride, titanium dioxide (E171), iron oxide red (E172) and iron oxide black (E172).
- Contents in Dutasterided soft capsules: Glycerol monocaprylocaprate (Type-I) and butylhydroxytoluene (E321). Soft capsule shell: Gelatin (160 bloom), glycerol, titanium dioxide (E171) and 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 laurilsulfate and 2.3% polysorbate 80), triacetin and calcium stearate.
- Printing ink (Black): Shellac (E904), black iron oxide (E172) and potassium hydroxide.

- **What does the medicine look like and what is the content of the package:**

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.

Package type: The medicine is supplied in two package forms as detailed:

A carton package containing plastic trays, with a total of 30 hard capsules.

A plastic bottle containing 30 hard capsules.

Not all package sizes may be marketed.

Name of Manufacturer and its address:

Aurobindo Pharma Ltd., 2 Maitrivihar, Ameerpet, Hyderabad, India.

License holder and its address: Inovamed Pharma Ltd., P.O.B. 2349, Bnei Brak 5112202.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 166-79-36462.