

Package leaflet: Information for the patient

Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg Hard Capsules dutasteride/tamsulosin hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules is and what it is used for

Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules 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.

Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules is 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 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 (*acute urinary retention*). This requires immediate medical treatment. Sometimes surgery is necessary to remove or reduce the size of the prostate gland.

Dutasteride lowers the production of a 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 your prostate gland, making it easier to pass urine and rapidly improving your symptoms

2. What you need to know before you take Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules

Do not take Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules

- if you're a **woman** (because **this medicine is for men only**).
- if you're a **child or adolescent less than 18 years old**.
- if you're **allergic to dutasteride**, other **5-alpha reductase inhibitors**, **tamsulosin**, **soya**, **peanut** or to any of the other ingredients of this medicine (listed in section 6).
- if you have **low blood pressure** which makes you feel dizzy, lightheaded or faint (*orthostatic hypotension*).
- if you have a **severe liver disease**.

→ If you think any of these apply to you, **don't take** this medicine until you have checked with your doctor.

Warnings and precautions

Talk to your doctor before taking Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules:

- 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 about liver problems.** If you have had any illness affecting your liver, you may need some additional check-ups while you are taking Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules.
- **Make sure your doctor knows if you have severe problems with your kidney.**
- **Cataract (cloudy lens) surgery.** If you are going to have surgery to remove a cataract, your doctor may ask you to stop taking Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules for a while before your operation. Tell your eye specialist before your operation that you are taking Dutasteride/Tamsulosin Hydrochloride 0.5mg/0.4mg hard capsules or tamsulosin (or have previously taken it). Your specialist will need to take appropriate precautions to help prevent complications during your operation.
- **Women, children and adolescents** must not handle leaking Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules 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.** Dutasteride has been found in the semen of men taking Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules. 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 baby. Dutasteride has been shown to decrease sperm count, semen volume and sperm motility. This could reduce your fertility.

- **Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules 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 the test to detect prostate cancer. If you are having a blood test for PSA, tell your doctor that you are taking Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules. **Men taking Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules should have their PSA tested regularly.**
- In a clinical 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. The effect of Dutasteride on this serious form of prostate cancer is not clear.
- **Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules 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.

→ **Contact your doctor or pharmacist** if you have any questions about taking Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules.

Other medicines and Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Don't take Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules with these medicines:

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

Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules is not recommended with these medicines:

- **ketoconazole** (used to treat fungal infections)

Some medicines can react with Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules 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) such as vardenafil, sildenafil citrate and tadalafil
- **verapamil or diltiazem** (for high blood pressure)
- **ritonavir or indinavir** (for HIV)
- **itraconazole or ketaconazole** (for fungal infections)
- **nefazodone** (an antidepressant)
- **cimetidine** (for stomach ulcers)
- **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.

Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules with food and drink

Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules should be taken 30 minutes after the same meal each day.

Pregnancy, breast-feeding and fertility

Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules **must not be taken by women.**

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. This is a particular risk in the first 16 weeks of pregnancy.

→ **Contact your doctor** for advice if a pregnant woman has come into contact with Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules.

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

Dutasteride/Tamsulosin has been shown to reduce sperm count, semen volume and sperm movement. Therefore, male fertility may be reduced.

Driving and using machines

Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules makes some people dizzy, so it may affect your ability to drive or operate machinery safely.

→ **Do not drive or operate machinery** if you are affected in this way.

Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules contains sunset yellow FCF (E110), lecithin from soya and sodium

Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules contains the colouring agent sunset yellow FCF (E110) which may cause allergic reactions.

Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules contains lecithin from soya. If you are allergic to peanut or soya, do not use this medicinal product.

Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium free'.

3. How to take Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules

Always take this medicine exactly as your doctor or pharmacist has told you. If you do not take it regularly the monitoring of your PSA levels may be affected. Check with your doctor or pharmacist if you are not sure.

How much to take

The recommended dose is one capsule taken once a day, 30 minutes after the same meal each day.

How to take

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

If you take more Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules than you should

Contact your doctor or pharmacist for advice if you take too many Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules capsules.

If you forget to take Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules

Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

Do not stop Dutasteride/Tamsulosin Hydrochloride 0.5 mg/ 0.4mg hard capsules without advice

Do not stop taking Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules without talking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reaction

The signs of allergic reactions can include:

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

→ **Contact your doctor immediately** if you get any of these symptoms, and **stop using Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules.**

Dizziness, light-headedness and fainting

Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules can cause dizziness, lightheadedness 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 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 a doctor immediately** if you get these symptoms and **stop using Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules.**

Common side effects (may affect up to 1 in 10 people)

- impotence (*not able to achieve or maintain an erection*)*
- decreased sex drive (*libido*)*
- difficulty with ejaculation, such as a decrease in the amount of semen released during sex*
- breast enlargement or tenderness (*gynecomastia*)
- dizziness.

* In a small number of people some of these events may continue after you stop taking Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules.

Uncommon side effects (may affect up to 1 in 100 people)

- 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 heart beat (*palpitations*)
- constipation, diarrhoea, vomiting, feeling sick (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 (may affect up to 1 in 1,000 people)

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

Very rare side effects (may affect up to 1 in 10,000 people)

- persistent painful erection of the penis (*priapism*)
- serious skin reactions (*Stevens-Johnson syndrome*)

Other side effects

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

- abnormal or fast heartbeat (*arrhythmia or tachycardia or atrial fibrillation*)
- shortness of breath (*dyspnoea*)
- depression
- pain and swelling in your testicles
- nose bleeds
- severe skin rash
- changes in vision (*blurred vision or visual impairment*)
- dry mouth

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +3531 6767836; Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules

Keep this medicine out of the sight and reach of children.

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

For HDPE bottles, do not use longer than 6 weeks for 30 capsules packsize and longer than 18 weeks for 90 capsules packsize, after first opening.

Do not store Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules contains

- The active substances are dutasteride and tamsulosin hydrochloride. Each capsule contains 0.5 mg dutasteride and 0.4 mg tamsulosin hydrochloride.
- The other ingredients (excipients) are:
 - hard capsule shell: hypromellose, carrageenan (E407), potassium chloride, titanium dioxide (E171), iron oxide red (E172), sunset yellow FCF (E110).
 - Inside the hard capsule: glycerol monocaprylocaprate and butylhydroxytoluene (E321), gelatin, glycerol, iron oxide yellow (E172), triglycerides (medium chain), lecithin (may contain soya oil) (E322), cellulose microcrystalline, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30%, methacrylic acid-ethyl acrylate copolymer (1:1), magnesium stearate, sodium hydroxide, triacetin, talc, titanium dioxide (E171).

What Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules looks like and contents of the pack

This medicine is an oblong, around 24 mm length, hard capsules with a brown body and an orange cap.

They are available in packs of 7, 28, 30 and 90 capsules placed either in HDPE bottles or aluminium/aluminium blisters.

Not all pack sizes may be available in your country.

Marketing Authorisation Holder

Accord Healthcare Ireland Limited,
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Ireland

Manufacturer:

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This medicinal product is authorised in the Member States of the EEA under the following names:

Malta	Dutasteride/Tamsulosin Accord 0.5 mg/0.4 mg Hard Capsules
Belgium	Dutasteride/Tamsulosin Accord 0.5 mg/0.4 mg, gélules
Bulgaria	Dutasteride/Tamsulosin Accord 0.5mg /0.4 mg Hard Capsules
Czech Republic	Dutasteride/Tamsulosin Accord
Estonia	Dutasteride/Tamsulosin Accord
Spain	Dutasterida/Tamsulosina Accord 0,5 mg/0,4 mg Cápsulas duras EFG
Finland	Dutasteride/Tamsulosin hydrochlorid Accord 0,5 mg/0,4 mg kovat kapselit
France	Dutasteride/Tamsulosin Accord 0.5 mg/0.4 mg, gélule
Hungry	Dutasterid/Tamsulozin Accord 0,5 mg/0,4 mg tvrde kapsule
Ireland	Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules
Italy	Dutasteride e Tamsulosina Accord
Lithuania	Dutasteride/Tamsulosin Accord 0,5 mg/0,4 mg kietosios kapsulės
Latvia	Dutasteride/Tamsulosin Accord 0.5 mg/0.4 mg Hard Capsules
Netherlands	Dutasteride/Tamsulosine HCl Accord 0,5 mg/0,4 mg harde capsules
Poland	Dutasteride/Tamsulosin Accord
Portugal	Dutasteride/Tamsulosin Accord 0,5 mg/0,4 mg cápsulas
Romania	Dutasteridă/Tamsulosin Accord 0,5 mg/0,4 mg capsule
United Kingdom	Dutasteride/Tamsulosin 0.5 mg/0.4 mg Hard Capsules

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