

## Package Leaflet: Information for the user

### Dutasteride/Tamsulosin hydrochloride 0.5mg/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:**

1. What Dutasteride/Tamsulosin hydrochloride is and what it is used for
2. What you need to know before you take Dutasteride/Tamsulosin hydrochloride
3. How to take Dutasteride/Tamsulosin hydrochloride
4. Possible side effects
5. How to store Dutasteride/Tamsulosin hydrochloride
6. Contents of the pack and other information

#### **1. What Dutasteride/Tamsulosin hydrochloride is and what it is used for**

**Dutasteride/Tamsulosin hydrochloride 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 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**

##### **Do not take Dutasteride/Tamsulosin hydrochloride**

- 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

- 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.
  - **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 for a while before your operation. Tell your eye specialist before your operation that you are taking Dutasteride/Tamsulosin hydrochloride 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 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. 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 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. **Men taking Dutasteride/Tamsulosin hydrochloride 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 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.

### Other medicines and Dutasteride/Tamsulosin hydrochloride

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

Don't take Dutasteride/Tamsulosin hydrochloride with these medicines:

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

Dutasteride/Tamsulosin hydrochloride is not recommended with these medicines:

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

Some medicines can react with Dutasteride/Tamsulosin hydrochloride 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 with food**

Dutasteride/Tamsulosin hydrochloride should be taken 30 minutes after the same meal each day.

#### **Pregnancy, breast-feeding and fertility**

Dutasteride/Tamsulosin hydrochloride **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.

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

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

→ **Contact your doctor** for advice if a pregnant woman has come into contact with Dutasteride/Tamsulosin hydrochloride.

#### **Driving and using machines**

Dutasteride/Tamsulosin hydrochloride makes some people feel dizzy, so it may affect your ability to drive or operate machinery safely.

→ **Don't drive or operate machinery** if you are affected in this way.

#### **Dutasteride/Tamsulosin hydrochloride contains lecithin from soya, propylene glycol and sodium**

This medicine contains lecithin from soya, which may contain soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

This medicine contains 299 mg propylene glycol in each capsule.

### **3. How to take Dutasteride/Tamsulosin hydrochloride**

**Always take Dutasteride/Tamsulosin hydrochloride exactly as your doctor or pharmacist has told you to.** 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 than you should**

Contact your doctor or pharmacist for advice if you take too many Dutasteride/Tamsulosin hydrochloride capsules.

#### **If you forget to take Dutasteride/Tamsulosin hydrochloride**

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

#### **Don't stop Dutasteride/Tamsulosin hydrochloride without advice**

Don't stop taking Dutasteride/Tamsulosin hydrochloride 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.**

#### **Dizziness, light-headedness and fainting**

Dutasteride/Tamsulosin hydrochloride 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**.

### **Common side effects**

These may affect up to 1 in 10 men taking Dutasteride/Tamsulosin hydrochloride:

- 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.

### **Uncommon side effects**

These may affect up to 1 in 100 men

- 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**

These may affect up to 1 in 1,000 men

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

### **Very rare side effects**

These may affect up to 1 in 10,000 men

- 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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

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 and bottle after EXP. The expiry date refers to the last day of that month.

This medicinal does not require any special storage condition.

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 contains

The active substances are dutasteride and tamsulosin hydrochloride. Each hard capsule contains 0.5 mg dutasteride and 0.4 mg tamsulosin hydrochloride (equivalent to 0.367 mg of tamsulosin). The other ingredients are:

#### Hard capsule shell:

- Black iron oxide (E172)
- Red iron oxide (E172)
- Titanium dioxide (E171)
- Yellow iron oxide (E172)
- Gelatin

#### Contents in dutasteride soft capsule:

- Propylene glycol monocaprylate, type II
- Butylhydroxytoluene (E321)

#### Soft Capsule Shell:

- Gelatin
- Glycerol
- Titanium dioxide (E171)
- Triglycerides (medium chain)
- Lecithin (may contain soya oil) (see section 2)

#### Tamsulosin pellets:

- Methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 per cent (contains sodium laurilsulfate, polysorbate 80)
- Microcrystalline cellulose
- Dibutyl sebacate
- Polysorbate 80
- Colloidal hydrated silica

Calcium stearate

Black ink:

Shellac (E904)

Black iron oxide (E172)

Propylene glycol (E1520)

Concentrated ammonia solution, (E527)

Potassium hydroxide (E525)

See section 2 “ Dutasteride/Tamsulosin hydrochloride contains lecithin from soya and propylene glycol”.

**What Dutasteride/Tamsulosin hydrochloride looks like and contents of the pack**

This medicine is an oblong hard gelatin capsule, of 24.2 mm x 7.7 mm approx, with brown body and beige cap printed with C001 in black ink.

Each hard capsule contains tamsulosin hydrochloride modified release pellets and one dutasteride soft gelatin capsule.

They are available in packs of 7, 30 and 90 capsules.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder:

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Manufacturer:

Laboratorios LEÓN FARMA, SA

C/La Vallina, s/n, Polígono Industrial Navatejera

Villaquilambre-24008 (León)

SPAIN

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

Country	Invented Name
Belgium	Dutasteride/Tamsulosine Viatris 0,5 mg/ 0,4 mg, harde capsules
Bulgaria	Dutamyl
Czech Republic	TARIS
France	Dutastéride/Tamsulosine Viatris 0,5 mg/0,4 mg, gélule
Germany	Dutasterid/Tamsulosin Mylan 0,5 mg/0,4 mg Hartkapseln
Estonia	Dutasteride/Tamsulosin Viatris
Spain	Dutasterida/Tamsulosina Viatris 0,5 mg/0,4 mg cápsulas duras EFG
Ireland	Dutasteride/Tamsulosin hydrochloride 0.5 mg/0.4 mg hard capsules
Finland	Dutasteride/Tamsulosinhydrochloride Viatris 0.5 mg/0.4 mg
Croatia	VASGAR
Lithuania	Dutasteride/Tamsulosin Viatris 0,5 mg/0,4 mg kietosios kapsulės
Luxembourg	Dutasteride/Tamsulosine Viatris 0,5 mg/0,4 mg gélules
Latvia	Dutasteride/Tamsulosin Viatris 0,5 mg/0,4 mg cietās Kapsulas
Netherlands	Dutasteride/Tamsulosine HCL Viatris 0,5 mg/0,4 mg, harde capsules
Norway	Dutasteride/Tamsulosin Viatris
Portugal	Dutasterida + Tansulosina Mylan
United Kingdom	Dutasteride/Tamsulosin hydrochloride 0.5 mg/0.4 mg hard capsule

**This leaflet was last revised in February 2023.**