

Package leaflet: Information for the user

Dutasteride/Tamsulosinehydrochloride 0,5 mg/0,4 mg, harde 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 of the 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 <Invented name> is and what it is used for
2. What you need to know before you take <Invented name>
3. How to take <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

1. What <Invented name> is and what it is used for

<Invented name> 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.

<Invented name> 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 < Invented name>

Do not take <Invented name>:

- if you are a **woman** (because **this medicine is for men only**).
- if you are a **child or adolescent less than 18 years old**.
- if you are **allergic to dutasteride**, other **5-alpha reductase inhibitors**, **tamsulosin**, **soya**, **peanut** or 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, **do not take** this medicine until you have checked with your doctor.

Warnings and precautions

Talk to your doctor before taking <Invented name>

- 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 <Invented name>.
- **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 <Invented name> for a while before your operation. Tell your eye specialist before your operation that you are taking <Invented name> 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 <Invented name> 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 the combination of dutasteride-tamsulosin. 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.
- **<Invented name> 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 <Invented name>. **Men taking < Invented named> should have their PSA tested regularly.**
- In a clinical study of men at increased risk of prostate cancer, men taking dutasteride have 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.
- **<Invented name> 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 <Invented name>.

Other medicines and < Invented name>

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

Do not take <Invented name> with these medicines:

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

<Invented name> is not recommended with these medicines:

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

Some medicines can react with <Invented name> and may make it more likely that you will have side-effects. These medicines include:

- **PDE5 inhibitors** (used to help achieve or maintain an erection) such as **ildenafil citrate and tadalafil**
- **verapamil or diltiazem** (for high blood pressure)
- **ritonavir or indinavir** (for HIV)
- **itraconazole or ketoconazole** (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.

<Invented name> with food and drink

<Invented name> should be taken 30 minutes after the same meal each day.

Pregnancy, breast-feeding and fertility

<Invented name> **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 the combination of dutasteride-tamsulosin. If your partner is or may be pregnant, you must avoid exposing her to your semen.

The combination of dutasteride-tamsulosin 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 <Invented name>

Driving and using machines

<Invented name> makes some people feel 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.

<Invented name> contains lecithin from soya

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.

<Invented name> contains propylene glycol

This medicine contains 299.46 mg propylene glycol monocaprylate, type II in each capsule (equivalent to more than 1 mg/kg/day, but less than 50 mg/kg/day of propylene glycol) and traces of propylene glycol in the black ink.

<Invented name> contains sodium

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

3. How to take <Invented name>

Always take <Invented name> 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 <Invented name> than you should

Contact your doctor or pharmacist for advice if you take too many <Invented name> capsules.

If you forget to take <Invented name>

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 <Invented name> without advice

Do not stop taking <Invented name> 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 <Invented name>

Dizziness, light-headedness and fainting

<Invented name> 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 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 <Invented name>**

Common side effects

May affect up to 1 in 10 men:

- 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 <Invented name>

Uncommon side effects

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 heartbeat (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 men:

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

Very rare side effects

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

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

Store below 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 <Invented name> contains

- The active substances are dutasteride and tamsulosin hydrochloride. Each hard capsule contains 0.5 mg dutasteride (in a soft capsule) and 0.4 mg tamsulosin hydrochloride (as modified release pellets).

- The other ingredients are:

Hard Capsule Shell:

Black iron oxide (E172)

Red iron oxide (E172)

Titanium dioxide (E171)

Yellow iron oxide (E172)

Gelatin

Black ink (shellac, black iron oxide (E172), propylene glycol, ammonia solution, concentrated, potassium hydroxide)

Contents of dutasteride Soft Capsules:

Propylene glycol monocaprylate, type II (see section 2 “<Invented name> contains propylene glycol”)

Butylhydroxytoluene (E321)

Gelatin

Glycerol

Titanium dioxide (E171)

Triglycerides (medium chain)

Lecithin (may contain soya oil, see section 2 “<Invented name> contains lecithin from soya”).

Contents of Tamsulosin Pellets

Methacrylic acid - ethyl acrylate copolymer 1:1 dispersion 30 per cent (contains sodium laurilsulfate and polysorbate 80, see section 2 “<Invented name> contains sodium”)

Cellulose microcrystalline

Dibutyl sebacate

Polysorbate 80

Silica colloidal hydrated
Calcium stearate

What <Invented name> looks like and contents of the pack

This medicine is an oblong hard capsule with brown body and orange cap printed with C001 in black ink and approximately 21 mm in length.

Pack sizes:

HDPE bottles: 7, 30, 90 and 180 (2 bottles of 90) capsules.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen

Teva B.V.
Swensweg 5
2031 GA Haarlem
Nederland

Fabrikant

Laboratorios León Farma, SA
c/La Vallina, s/n, Polígono Industrial Navatejera,
24193, Villaquilambre, León
Spanje

In het register ingeschreven onder

RVG 123562

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland	Dutasteride/Tamsulosinehydrochloride Teva 0,5 mg/0,4 mg, harde capsules
Portugal	Dutasterida + Tansulosina ratiopharm
Spanje	Dutasterida/Tamsulosina ratio 0,5 mg/0,4 mg capsulas duras EFG
Bulgarije	Тамсудил Дуо 0.5 mg/0.4 mg твърди капсули Tamsudil Duo 0.5 mg/0.4 mg hard capsules
Hongarije	Tamsudil Duo 0,5mg/0,4 mg kemény kapszula
Noorwegen	Dutasterid/Tamsulosin Teva

Deze bijsluiter is voor het laatst goedgekeurd in november 2024.