

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dutasteride/Tamsulosin Rowa 0.5 mg/0.4 mg hard capsules Dutasteride/tamsulosinhydrochloride

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 include any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Dutasteride/Tamsulosin Rowa is and what it is used for

Dutasteride/Tamsulosin Rowa 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 Rowa 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 you are not treated, 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 reduce the prostate size and relieve the symptoms. This will reduce the risk of acute urinary retention and the need for surgery. Tamsulosin acts by relaxing the muscle tissue in your prostate gland, making it easier to pass urine and rapidly improving your symptoms.

2. Before you take Dutasteride/Tamsulosin Rowa

Do not take Dutasteride/Tamsulosin Rowa

- **if you are allergic (hypersensitive) 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.**

Tell your doctor if you think any of these apply to you.

This medicine is for men only. It must not be taken by women, children or adolescents.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dutasteride/Tamsulosin Rowa

- In some clinical studies, the number of patients who experienced heart failure was higher in patients taking dutasteride and another medicine called an alpha-blocker (like tamsulosin), than patients taking only dutasteride or only an alpha blocker. Heart failure means your heart does not pump blood properly.
- 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 Rowa.
- 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 Rowa for a while before your operation. Tell your eye specialist before your operation that you are taking Dutasteride/Tamsulosin Rowa 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 Rowa capsules, because the active ingredient can be absorbed through the skin. Wash up 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 analysis of men taking Dutasteride/Tamsulosin Rowa. 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 Rowa 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 Rowa. Men taking Dutasteride/Tamsulosin Rowa should have their PSA tested regularly.

- In a clinical study of men with high risk of prostate cancer, men taking dutasteride have a serious type of prostate cancer more often than men who did not take dutasteride.

The effect of dutasteride on this serious type of prostate cancer is not clear.

- Dutasteride/Tamsulosin Rowa may cause breast enlargement and tenderness. If this becomes troublesome, or if you notice breast lumps or nipple pain you should talk to your doctor about these changes as these may be signs of a serious condition, such as breast male cancer.

Mood changes and depression

Depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients taking another medicine from the same therapeutic class (5-alpha reductase inhibitor) by mouth. If any of these symptoms occur, contact your doctor for further medical advice as soon as possible.

Other medicines and Dutasteride/Tamsulosin Rowa.

Tell your doctor if you are taking, or have recently taken, any other medicines. This includes any medicines you have bought without a prescription.

Do not take Dutasteride/Tamsulosin Rowa with these medicines:

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

Dutasteride/Tamsulosin Rowa is not recommended with these medicines:

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

Some medicines can react with Dutasteride/Tamsulosin Rowa and 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)
- **itraconazole or ketoconazole** (for fungal infections)
- **nefazodone** (an antidepressant)
- **cimetidine** (for stomach ulcers)
- **warfarin** (for blood clotting)
- **erythromycin** (an antibiotic used to treat infections)
- in combination with **paroxetine** (an antidepressant)
- **terbinafine** (for fungal infections)
- **diclofenac** (for treatment of pain and inflammation).

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

Dutasteride/Tamsulosin Rowa with food and drink

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

Pregnancy, breast-feeding and fertility

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 analysis of men taking Dutasteride/Tamsulosin Rowa. If your partner is or may be pregnant, you must avoid exposing her to your semen.

Dutasteride/Tamsulosin Rowa 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 Rowa

Driving and using machines

Dutasteride/Tamsulosin Rowa 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.

Dutasteride/Tamsulosin Rowa 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'.

Dutasteride/Tamsulosin Rowa contains propylene glycol

This medicine contains 299.46 mg propylene glycol in each capsule.

3. How to take Dutasteride/Tamsulosin Rowa

Always take Dutasteride/Tamsulosin Rowa exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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

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 Rowa than you should

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

If you forget to take Dutasteride/Tamsulosin Rowa

Do not take extra capsules to make up for a missed dose. Just take your next dose at the usual time.

If you stop taking Dutasteride/Tamsulosin Rowa

Do not stop taking Dutasteride/Tamsulosin Rowa without talking to your doctor first.

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

4. Possible side effects

Like all medicines, Dutasteride/Tamsulosin Rowa 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 Rowa**

Dizziness, light-headedness and fainting

Dutasteride/Tamsulosin Rowa can cause dizziness, light-headedness and on rare occasions fainting. Take care when moving from a lying down or sitting position to 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 Rowa.**

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

- impotence (not able to achieve or maintain an erection) *
- decreased sex drive (*libido*)*
- difficulty with ejaculation*
- breast enlargement or tenderness
- dizziness.

*In a small number of people some of these effects may continue after you stop taking Dutasteride/Tamsulosin Rowa.

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

- 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 patients*)

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

Very rare side effects

(*may affect up to 1 in 10,000 patients*)

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

Other side effects

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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie;

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dutasteride/Tamsulosin Rowa

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

Do not use Dutasteride/Tamsulosin Rowa after the expiry date which is stated on the carton and the bottle. The expiry date refers to the last day of that month.

Do not store Dutasteride/Tamsulosin Rowa above 30°C.

Shelf life after first opening of the tablet container is 90 days.

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. Further information

What Dutasteride/Tamsulosin Rowa 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 are:

Hard Capsule Shell:

Black iron oxide (E172)
Red iron oxide (E172)
Titanium Dioxide (E171)
Yellow iron Oxide (E172)
Gelatine.

Capsule contents:

Propylene Glycol Monocaprylate
Butylhydroxytoluene.

Capsule shell:

Gelatin
Glycerol
Titanium dioxide (E171)
Triglycerides (medium chain)
Lecithin (may contain soya oil).

Tamsulosin Pellets:

Methacrylic acid - ethyl acrylate copolymer 1:1 dispersion 30 per cent
Cellulose Microcrystalline
Dibutyl Sebacate
Polysorbate 80
Silica colloidal anhydrous
Calcium stearate.

Black Inks:

Shellac
Black Iron Oxide (E172)
Propylene Glycol
Strong ammonia solution
Potassium Hydroxide.

What Dutasteride/Tamsulosin Rowa looks like and contents of the pack

This medicine is an oblong hard capsule with brown body and beige cap printed with C001 in black ink. They are available in packs of 7, 30 and 90 capsules.

Not all pack sizes may be available in your country.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Rowa Pharmaceuticals Ltd.
Bantry
Co Cork
Ireland.

Manufacturer:

Laboratorios LEÓN FARMA, SA
Polígono Industrial Navatejera
C/La Vallina, s/n -24193 Navatejera -León
SPAIN.

This leaflet was last revised in October 2025