

Package leaflet: Information for the user

Dutasteride Rowa 0.5 mg soft capsules

Dutasteride

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

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

Dutasteride 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.

The active ingredient of this medicine is dutasteride. It belongs to a group of medicines called 5-alpha reductase inhibitors.

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. In some situations surgery is necessary to remove or reduce the size of the prostate gland. Dutasteride Rowa lowers the production of 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.

Dutasteride Rowa may also be used with another medicine called tamsulosin (used to treat the symptoms of an enlarged prostate).

2. What you need to know before you take Dutasteride Rowa

Do not take Dutasteride Rowa

- if you are allergic to dutasteride, other 5-alpha reductase inhibitors, or to any of the other ingredients of this medicine (listed in section 6). This medicinal product may contain lecithin from soya oil. If you are allergic to peanut or soya do not use this medicine
- if you have a severe liver disease
- this medicine is for men only. It must not be taken by women, children or adolescents.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Dutasteride Rowa

- 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 Rowa.
- Women, children and adolescents must not handle leaking Dutasteride Rowa 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 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 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 Rowa. Men taking Dutasteride Rowa should have their PSA tested regularly.
- In a clinical study of men at increased risk of prostate cancer, men taking Dutasteride Rowa had a serious form of prostate cancer more often than men who did not take Dutasteride Rowa. The effect of Dutasteride Rowa on this serious form of prostate cancer is not clear.
- Dutasteride Rowa 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.

Mood alterations and depression

Mood alterations including depressed mood, depression and, less frequently, suicidal ideation have been reported in patients treated with another oral 5-alpha reductase inhibitor. Patients should be advised to seek medical advice if any of these symptoms occur.

→ Contact your doctor or pharmacist if you have any questions about taking Dutasteride Rowa.

Children and adolescents

This medicine is for men only. Leaking capsules must not be handled by women, children or adolescents.

Other medicines and Dutasteride Rowa

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

Some medicines can react with Dutasteride Rowa and may increase the risk of side-effects. These medicines include:

- verapamil or diltiazem (for high blood pressure)
- ritonavir or indinavir (for HIV)
- itraconazole or ketoconazole (for fungal infections)
- nefazodone (an antidepressant)
- alpha-blockers (for enlarged prostate or high blood pressure).

→ Tell your doctor if you are taking any of these medicines. Your dose of Dutasteride Rowa may need to be reduced.

Dutasteride Rowa with food and drink

Dutasteride Rowa can be taken with or without food.

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

Dutasteride 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.

Driving and using machines

Dutasteride Rowa is unlikely to affect your ability to drive or operate machinery.

Dutasteride Rowa contains lecithin from soya

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

This medicine contains 299.46 mg propylene glycol in each capsule.

3. How to take Dutasteride Rowa

Always take this medicine exactly as your doctor or pharmacist 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.

The recommended dose

The usual dose is one capsule (0.5 mg) taken once a day. 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. The capsules may be taken with or without food.

Dutasteride Rowa is a long term treatment. Some men notice an early improvement in their symptoms. However, others may need to take Dutasteride Rowa for 6 months or more before it begins to have an effect. Keep taking Dutasteride Rowa for as long as your doctor tells you.

Hepatic impairment

If you have liver problems (mild to moderate), ask your doctor or pharmacist. The use of Dutasteride Rowa is not recommended in patients with severe liver disease (see section "Do not take Dutasteride Rowa").

If you take more Dutasteride Rowa than you should

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

If you forget to take Dutasteride Rowa

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

If you stop taking Dutasteride Rowa

Do not stop taking Dutasteride Rowa without talking to your doctor first. It may take up to 6 months or more for you to notice an effect.

➔ 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 Rowa.

Common (may affect up to 1 in 10 men):

- not able to achieve or maintain an erection (*impotence*), this may continue after you stop taking Dutasteride Rowa
- decreased sex drive (*libido*), this may continue after you stop taking Dutasteride Rowa
- difficulty with ejaculation, this may continue after you stop taking Dutasteride Rowa
- breast enlargement or tenderness (*gynecomastia*)
- dizziness when taken with tamsulosin.

Uncommon (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).
- hair loss (usually from the body) or hair growth.

Not known (frequency cannot be estimated from the available data):

- depressed mood
- pain and swelling in your testicles.

Reporting 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 HPRAs 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 Rowa

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 the foil blister strip. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original carton in order to protect from light and moisture.

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 Rowa contains

- The active substance is dutasteride. Each soft capsule contains 0.5 mg dutasteride.
- The other ingredients are:
 - inside the capsule: propylene glycol monocaprylate and butylated hydroxytoluene.
 - capsule shell: gelatin, glycerol, titanium dioxide (E171),

What Dutasteride Rowa looks like and contents of the pack

Dutasteride Rowa soft capsules are oblong soft gelatine capsules (approximately 16.5 x 6.5 mm) of light yellow colour, filled with transparent liquid. They are available in packs (transparent triplex (PVC-PE-PVDC)/Aluminium blister) of 30, 60 and 90 capsules.

Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Rowa Pharmaceuticals Ltd.
Bantry
Co Cork
P75V009
Ireland

Manufacturer:

Laboratorios LEÓN FARMA, SA
C/ La Vallina, s/n,
Polígono Industrial Navatejera,
24193 Villaquilambre (León), SPAIN

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