

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

UROKA

Dutasteride Capsules 0.5 mg

Read all of this leaflet carefully before you start using this medicine.²

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

- a) What UROKA is and what it is used for
- b) Before you take UROKA
- c) How to take UROKA
- d) Possible side effects
- e) How to store UROKA
- f) Further information

a) WHAT UROKA IS AND WHAT IT IS USED FOR

UROKA contains the active ingredient is Dutasteride. It belongs to a group of medicines called 5-alpha reductase inhibitors.

It 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.

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. UROKA 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.

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

b) BEFORE YOU TAKE UROKA

Do not take UROKA

- if you are allergic (hypersensitive) to dutasteride, other 5-alpha reductase inhibitors, or any of the other ingredients of UROKA.
- 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.

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

Take special care with UROKA

Talk to your doctor before taking UROKA.

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

Taking with other medicines

Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines can react with UROKA and may make it more likely that you'll have 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 UROKA may need to be reduced.

Taking UROKA with food and drink

UROKA can be taken with or without food.

Pregnancy and breast-feeding

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 UROKA. If your partner is or may be pregnant, you must avoid exposing her to your semen.

UROKA 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

UROKA is unlikely to affect your ability to drive or operate machinery

c) HOW TO TAKE UROKA

Always take UROKA 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 (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.

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

If you take more UROKA than you should

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

If you forget to take UROKA

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 UROKA

Don't stop UROKA without advice: Don't stop taking UROKA without talking to your doctor first. It may take up to 6 months or more for you to notice an effect.

d) POSSIBLE SIDE EFFECTS

Like all medicines, UROKA 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 UROKA.

Common side effects

These may affect up to 1 in 10 men taking UROKA:

- not able to achieve or maintain an erection (*impotence*), this may continue after you stop taking UROKA.
- decreased sex drive (*libido*), this may continue after you stop taking UROKA.
- difficulty with ejaculation, such as a decrease in the amount of semen released during sex, this may continue after you stop taking UROKA.
- breast enlargement or tenderness (*gynecomastia*)
- dizziness when taken with tamsulosin.

Uncommon side effects

These may affect up to 1 in 100 men taking UROKA:

- 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 side effects

The frequency cannot be estimated from the available data:

- depression
- pain and swelling in your testicles.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

e) HOW TO STORE UROKA

- Storage

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

Store below 30°C in a dry place.

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.

- Disposal

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.

f) FURTHER INFORMATION

What UROKA contains:

- The active pharmaceutical ingredient is Dutasteride. Each soft gelatin capsule contains 0.5 mg dutasteride.
- The other inactive ingredients are Mono-and Di-glycerides (Capmul MCM NF), Butylhydroxytoluene.
- Capsule shell ingredients: Gelatin, Glycerine, Iron oxide yellow, Titanium dioxide, Purified water.

What UROKA looks like and contents of the pack:

Colorless, oily liquid filled in 10 minim, oblong, opaque yellow, soft gelatin shell capsule.

UROKA capsules are available as 10 capsules in a blister, 3 blisters are packed in a printed unit carton with a literature insert.

Marketing Authorization Holder and Manufacturing Site Addresses:

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