

UROKA DUTASTERIDE SOFT GELATIN CAPSULES 0.5MG

Dutasteride (0.5 mg)

What is in this leaflet

1. What UROKA is used for
2. How UROKA works
3. Before you use UROKA
4. How to use UROKA
5. While you are using it
6. Side effects
7. Storage and Disposal of UROKA
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP revision
11. Serial No.

What UROKA is used for

UROKA 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*.

How UROKA works

The active ingredient 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. 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).

Before you use UROKA

- *When you must not use it*

Do not take this medicine if:

- you are allergic to *Dutasteride*, other 5-alpha reductase inhibitors, or to any of the other ingredients of this medicine.
- you have a severe liver disease.
- you are women, children and adolescents. This medicine is for adult men only.

If you think any of these apply to you, don't take this medicine until you have checked with your doctor.

- *Before you start to use it*

Check with your doctor or pharmacist before taking UROKA if you have had any illness affecting your liver, you may need some additional check-ups while you are taking UROKA.

Contact your doctor or pharmacist if you have any questions about taking UROKA.

- *Taking other medicines*

Tell your doctor if you are taking any other medicines, or have recently taken any. This includes medicines bought without a prescription from a pharmacy, supermarket or health food shop.

Some medicines can react with UROKA and may make it more likely that you will 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* (antidepressant)
- alpha blockers (for enlarged prostate or high blood pressure).

Tell your doctor if you are taking or have recently taken any of these medicines. Your dose of UROKA may need to be reduced.

How to use UROKA

- *How much to use*

The recommended dose is one capsule (0.5 mg) taken once a day. Swallow the

capsule with water. Do not chew or break open the capsule. Contact with the contents of the capsule may make your mouth or throat sore. UROKA can be taken with or without food.

- *When to use it*

Always take UROKA exactly as your doctor or pharmacist has told you. 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 long to use it*

UROKA is 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. Do not stop taking UROKA without talking to your doctor first.

- *If you forget to use it*

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*

Contact your doctor or pharmacist for advice or go to the Emergency Department of your nearest hospital, if you take too many UROKA capsules. If possible, show them the UROKA pack.

While you are using UROKA

- *Things you must do*

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.

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- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

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.

Do not donate blood while taking *Dutasteride* and for at least 6 months after your treatment ends. *Dutasteride* can be carried in the blood and could cause birth defects if a pregnant woman receives a transfusion with blood that contains *Dutasteride*.

- Things to be careful of

- **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 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.

Driving and using machines

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

Side effects

Like all medicines, UROKA can cause side effects although not everybody gets them.

Contact your doctor immediately if you get any of these symptoms, and stop using UROKA.

Common side effects

- 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*.

Rare side effects

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

Very rare side effects

- Allergic reactions including rash, pruritus, urticaria, localised oedema, and angioedema.
- Depressed mood.
- Pain and swelling in your testicles.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of 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

Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

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

- Ingredients

- Active ingredient

The active substance is *Dutasteride*. Each soft gelatin capsule contains 0.5mg *Dutasteride*.

- Inactive ingredients

Mono & diglycerides (Capmul MCM NF), gelatin, glycerin, purified water, titanium dioxide, iron oxide yellow and butylated hydroxytoluene (BHT).

- MAL number

MAL21066020ARZ

Manufacturers

- Packed and released by

GoodScience Sdn. Bhd.

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