

# UROKA PLUS HARD CAPSULES

Dutasteride/ Tamsulosin Hydrochloride (0.5mg/ 0.4mg)

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## WHAT UROKA PLUS IS USED FOR

UROKA Plus is used to treat men with moderate to severe symptoms of benign prostatic hyperplasia (BPH) - a non-cancerous growth of the prostate gland caused by producing too much of a hormone called DHT (*dihydrotestosterone*). UROKA Plus reduces the risk of acute urinary retention and the need for surgery in people with moderate to severe symptoms of BPH.

## HOW UROKA PLUS WORKS

UROKA Plus 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.

Dutasteride helps to shrink the prostate and relieve symptoms, by reducing the amount of DHT your body produces. Tamsulosin acts by relaxing the muscles in your prostate gland, making it easier to pass urine, and improving your symptoms.

## BEFORE YOU USE UROKA PLUS

### - When you must not use it

Do not use UROKA Plus

- if you are allergic (*hypersensitive*) to dutasteride, tamsulosin or to any of the other ingredients of UROKA Plus, or to other medicines known as 5-alpha reductase inhibitors.
- if you are female or age 21 years and below. This medicine is for adult men only.

If any of these apply to you, don't take UROKA Plus until you have checked with your doctor.

UROKA Plus must also not be taken by individuals with low blood pressure associated with feelings of dizziness upon getting up or standing (orthostatic hypotension), or by individuals with severe liver impairment.

### - Before you start to use it

Take special care with UROKA Plus

- In clinical studies with dutasteride, some individuals taking dutasteride and an alpha-blocker had heart failure more often than individuals taking only dutasteride or only an alpha-blocker. (Heart failure means your heart does not pump blood as well as it should.) Caution is advised in individuals with coronary heart disease and swallowing disorder.
- If you have mild to moderate liver disease, check with your doctor that UROKA Plus is suitable for you. You may need extra check-ups while you are taking UROKA Plus.
- If you have severe kidney impairment, incomplete bladder emptying and/or severely impaired urine flow.
- If you are going to have cataract (cloudy lens), glaucoma (increased eye pressure) surgery. Tell your doctor or eye specialist before your operation that you are taking, or have previously taken UROKA

Plus. They may ask you to temporarily stop taking UROKA Plus 1-2 weeks before your operation.

- Women, children and adolescents must not handle leaking UROKA Plus, 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.
- UROKA Plus 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.

### - Taking other medicines

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

Don't take UROKA Plus with these medicines:

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

UROKA Plus is not recommended with these medicines:

- ketoconazole, itraconazole, fluconazole (used to treat fungal infections)

Some medicines can interact with UROKA Plus and may make it more likely that you'll have side-effects. These medicines include:

- PDE5 inhibitors (used to help achieve or maintain an erection)
- warfarin (to prevent blood clotting)
- erythromycin, clarithromycin (antibiotics used to treat infections)
- verapamil, diltiazem, amiodarone (to treat irregular heart beat)
- cimetidine (to treat heartburn)
- paroxetine (an antidepressant)

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This is not a complete list of interactions. Tell your doctor or pharmacist if you are taking any medicines.

## HOW TO USE UROKA PLUS

Always take UROKA Plus exactly as your doctor has told you. Check with your doctor or pharmacist if you're not sure.

### - How much to use

The usual dose of UROKA Plus is one capsule (containing 0.5 mg dutasteride/0.4 mg tamsulosin) taken once a day.

### - When to use it

Swallow UROKA Plus capsule whole with some water, approximately 30 minutes after the same meal each day. Don't chew or open the capsules. Contact with the contents of the capsules may make your mouth or throat sore.

### - How long to use it

Take UROKA Plus for as long as your doctor recommends. Don't stop taking UROKA Plus without talking to your doctor first.

On discontinuing UROKA Plus the prostate can go back to the size it was prior to the treatment.

### - If you forget to use it

Don't take extra capsules to make up for a missed dose. Just take your next dose at the usual time.

### - If you use too much (overdose)

If you take too many UROKA Plus capsules, contact your doctor or pharmacist for advice. If possible, show them the UROKA Plus pack. Acute low blood pressure (systolic blood pressure 70 mmHg), vomiting and diarrhea were observed in these people.

## WHILE YOU ARE USING UROKA PLUS

### - Things you must do

- In a clinical study of men at increased risk of prostate cancer, men taking dutasteride had a serious form of prostate cancer more often than men who did not take dutasteride.
- A blood test to measure the amount of a substance called PSA (*prostate specific antigen*) in your blood can help your doctor to tell if you have prostate disease, including prostate cancer. If you have a higher than normal amount of PSA in your blood, it could mean that you have prostate cancer.
- Men taking UROKA Plus should have their PSA measured 6 months after starting treatment and regularly thereafter. Taking UROKA Plus will reduce the amount of PSA measured in your blood. You could still be at risk for prostate cancer even though your PSA is lower. Your doctor can still use PSA to help detect prostate cancer, by comparing your test results each time you have a PSA test.
- It is important to take your medicine as your doctor recommends. If you do not take it regularly, it may interfere with your doctor's ability to monitor your PSA.

### - Things you must not do

This medicine has been prescribed for you personally. Don't pass it on to other people – it may harm them even if their symptoms seem to be the same as yours.

### - Things to be careful of

#### *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.

Contact your doctor for advice if a pregnant woman has come into contact with the contents of a UROKA Plus capsule.

### *Male Fertility*

UROKA Plus has been shown to reduce sperm count, semen volume and sperm movement. However, it is not clear if male fertility is affected by UROKA Plus.

### *Driving and using machines*

UROKA Plus can make some people feel dizzy and have vision disturbance.

Don't drive or operate machinery unless you're feeling well.

## SIDE EFFECTS

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

*Dizziness, light-headedness and fainting:* UROKA Plus 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 light-headed at any time during treatment, sit or lie down until the symptoms pass.

*Allergic reactions:* Signs can include:

- raised and itchy rash (hives)
- swelling, sometimes of the face or mouth (angioedema) causing difficulty in breathing
- collapse

Contact a doctor immediately if you get any of these symptoms. Stop taking UROKA Plus.

*Serious skin reactions:* These may affect up to 1 in 10,000 people taking UROKA Plus. Signs can include:

- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).

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Contact a doctor immediately if you get any of these symptoms. Stop taking UROKA Plus.

*Common side effects:* These may affect up to 1 in 10 people:

- not able to achieve or maintain an erection
- decreased sex drive\*
- difficulty with ejaculation\*
- breast enlargement or tenderness

\* these events may continue after you stop taking UROKA Plus.

*Uncommon side effects:* These may affect up to 1 in 100 people:

- feeling of fast heartbeat
- constipation, diarrhoea, vomit, 2 nausea
- weakness or loss of strength
- itchy, blocked or runny nose

*Very rare side effects:* These may affect up to 1 in 10,000 people:

- persistent painful erection of the penis

Contact a doctor urgently if this happens to you. You may need to have treatment to avoid serious complications.

- depressed mood
- pain and swelling in your testicles

## *Other side effects*

Other side effects have occurred but their exact frequency is unknown:

- irregular or fast heartbeat
- shortness of breath
- breast cancer in men

If you get side effects, tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

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

## STORAGE AND DISPOSAL OF UROKA PLUS

### - *Storage*

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

Protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the carton or bottle or blister after EXP. The expiry date refers to the last day of that month.

Do not store UROKA Plus above 30°C.

### - *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.

## PRODUCT DESCRIPTION

### - *What it looks like*

Orange cap and brown body hard capsules containing white to off white pellets and one yellow soft gelatin capsule with an oily and yellowish liquid.

### - *Ingredients*

#### - Active Ingredient

The active substances are Dutasteride 0.5mg and Tamsulosin Hydrochloride 0.4mg.

#### - Inactive Ingredients

Hard Capsule Shell:

Hypromellose, Potassium Chloride, Carrageenan, Titanium Dioxide (E171), Sunset Yellow (E110), Red Iron Oxide (E172)

Contents in Dutasteride Soft Capsule:

Content in the Capsule: Glycerol monocaprylocaprate, Butylhydroxytoluene (E321)

Soft Capsule Shell:

Gelatin, Glycerol, Titanium Dioxide (E171), Iron Oxide Yellow (E172), Triglycerides (medium chain), Lecithin (soya) (E-322)

Tamsulosin Pellets:

Microcrystalline cellulose, Magnesium stearate, Methacrylic acid-ethyl acrylate copolymer 1:1 dispersion 30%, Sodium hydroxide, Triacetin, Purified Talc, Titanium Dioxide (E171)

### - *MAL number*

MAL24046039ACZ

## MANUFACTURER

SAG MANUFACTURING, S.L.U.  
Carretera Nacional 1 Km 36, San Agustin del Guadalix, 28750 Madrid, Spain.

## PRODUCT REGISTRATION HOLDER

MEGA LIFESCIENCES SDN. BHD.  
B-28-02, The Ascent, Paradigm.  
No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor, Malaysia.

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