



Dutasteride 0.5mg and Tamsulosin Hydrochloride 0.4mg hard capsule

MODULE 1: ADMINISTRATIVE INFORMATION AND PRODUCT INFORMATION

Uroka Plus

Dutasteride/tamsulosin hydrochloride
0.5/0.4mg hard capsules

Read all of this leaflet carefully before you start taking this medicine.

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

WHAT IS IN THIS LEAFLET

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

a) WHAT UROKA PLUS IS AND WHAT IT IS USED FOR

Uroka Plus is used to treat men with an enlarged prostate (benign prostatic hyperplasia) - a noncancerous growth of the prostate gland, caused by producing too much of a hormone called dihydrotestosterone.

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 (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 shrink the prostate and relieve the symptoms. This will reduce the risk of acute urinary retention and the need for surgery. Tamsulosin acts by relaxing the muscles in your prostate gland, making it easier to pass urine and rapidly improving your symptoms.

b) BEFORE YOU USE UROKA PLUS

Do not use Uroka Plus

- if you're a woman (because this medicine is for men only).
- if you're a child or adolescent less than 18 years old.
- if you're allergic to dutasteride, other 5-alpha reductase inhibitors, tamsulosin, soya, peanut or to any of the other ingredients of this medicine.
- if you have low blood pressure which makes you feel dizzy, lightheaded or faint (orthostatic hypotension).
- 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.

Take special care with Uroka Plus

Talk to your doctor before taking Dutasteride/Tamsulosin Hydrochloride Capsules.

- 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



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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/Tamsulosin Hydrochloride Capsules.
- **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 Hydrochloride Capsules for a while before your operation. Tell your eye specialist before your operation that you are taking Dutasteride/Tamsulosin Hydrochloride Capsules 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 Hydrochloride 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/Tamsulosin Hydrochloride Capsules. 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 Hydrochloride Capsules 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 Hydrochloride Capsules. **Men taking Dutasteride/Tamsulosin Hydrochloride Capsules should have their PSA tested regularly.**

- **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. The effect of dutasteride on this serious form of prostate cancer is not clear.
- **Dutasteride/Tamsulosin Hydrochloride Capsules 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 Dutasteride/Tamsulosin Hydrochloride Capsules.

Taking with other medicines

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

Don't take Dutasteride/Tamsulosin Hydrochloride Capsules with these medicines:

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

Dutasteride/Tamsulosin Hydrochloride Capsules are not recommended with these medicines:

- ketoconazole (used to treat fungal infections)

Some medicines can react with Dutasteride/Tamsulosin Hydrochloride Capsules and may make it more likely that you'll have side-effects. These medicines include:



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- PDE5 inhibitors (used to help 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)
- paroxetine (an antidepressant)
- terbinafine (used to treat fungal infections)
- diclofenac (used to treat pain and inflammation)

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

Taking Uroka Plus with food and drink
Dutasteride/Tamsulosin Hydrochloride Capsules should be taken 30 minutes after the same meal each day.

Pregnancy and breast-feeding
Dutasteride/Tamsulosin Hydrochloride Capsules must not be taken by women.

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

Dutasteride/Tamsulosin 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 Hydrochloride Capsules.

Driving and using machines
Dutasteride/Tamsulosin Hydrochloride Capsules make some people dizzy, so it may affect your ability to drive or operate machinery safely.

Don't drive or operate machinery if you are affected in this way.

Important information about some of the ingredients of Uroka Plus
Dutasteride/Tamsulosin Hydrochloride Capsules contains lecithin from soya. If you are allergic to peanut or soya, do not use this medicinal product.

c) HOW TO TAKE UROKA PLUS

Always take this medicine 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 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 Uroka Plus than you should
Contact your doctor or pharmacist for advice if you take too many Dutasteride/Tamsulosin Hydrochloride Capsules.

If you forget to take Uroka Plus
Do not take a double dose to make up for a forgotten dose. Just take your next dose at



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the usual time.

If you stop taking Uroka Plus

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

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

d) 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/Tamsulosin Hydrochloride Capsules.

Dizziness, light-headedness and fainting

Dutasteride/Tamsulosin Hydrochloride Capsules can cause dizziness, lightheadedness 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 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 Hydrochloride Capsules.

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

- impotence (not able to achieve or maintain an erection)*
- decreased sex drive (libido)*
- difficulty with ejaculation, such as a decrease in the amount of semen released during sex*
- breast enlargement or tenderness (gynecomastia)
- dizziness.

* In a small number of people some of these events may continue after you stop taking Dutasteride/Tamsulosin Hydrochloride Capsules.

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

- 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 people)

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

Very rare side effects (may affect up to 1 in 10,000 people)

- persistent painful erection of the penis (priapism)



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- serious skin reactions (Stevens-Johnson syndrome)

Other side effects

Other side effects have occurred in a small number of men, but their exact frequency is not known (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
- nose bleeds
- severe skin rash
- changes in vision (blurred vision or visual impairment)
- dry mouth

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

e) HOW TO STORE UROKA PLUS

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.

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 Plus contains

The active substances are dutasteride and tamsulosin hydrochloride. The hard capsules contain: One Dutasteride 0.5 mg soft gelatin capsule and Tamsulosin Hydrochloride pellets in the equivalent

weight of 0.4 mg of Tamsulosin Hydrochloride.

The other ingredients are:

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)

What Uroka Plus looks like and contents of the pack

Uroka Plus is available as hard capsules with brown body and orange cap.

Uroka Plus is available as alu-alu blister pack of 6 capsules. Such 5 blisters are packed in a carton.

MANUFACTURER FOR:

**MEGA LIFESCIENCES
(AUSTRALIA) PTY LTD**
Victoria 3810, Australia

MANUFACTURED BY:

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