

**PACKAGE LEAFLET**

## Package leaflet: Information for the patient

### Dutasteride Krka 0.5 mg capsules, soft 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 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 Krka is and what it is used for
2. What you need to know before you take Dutasteride Krka
3. How to take Dutasteride Krka
4. Possible side effects
5. How to store Dutasteride Krka
6. Contents of the pack and other information

#### **1. What Dutasteride Krka is and what it is used for**

Dutasteride Krka 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 Krka 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 Krka 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 Krka**

##### **Do not take Dutasteride Krka:**

- if you are allergic to dutasteride, other 5-alpha reductase inhibitors, soya, peanut or to any of the other ingredients of this medicine (listed in section 6);
- 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.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Dutasteride Krka.

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

### **Children and adolescents**

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

### **Other medicines and Dutasteride Krka**

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

Some medicines can react with Dutasteride Krka 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 Krka may need to be reduced.

### **Dutasteride Krka with food and drink**

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

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

### **Dutasteride Krka contains propylene glycol**

This medicine contains 299.46 mg propylene glycol in each soft capsule.

## **3. How to take Dutasteride Krka**

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 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. The capsules may be taken with or without food.

Dutasteride Krka is a long term treatment. Some men notice an early improvement in their symptoms. However, others may need to take Dutasteride Krka for 6 months or more before it begins to have an effect. Keep taking Dutasteride Krka 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 Krka is not recommended in patients with severe liver disease (see section "Do not take Dutasteride Krka").

### **If you take more Dutasteride Krka than you should**

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

### **If you forget to take Dutasteride Krka**

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 Krka**

Do not stop taking Dutasteride Krka 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 Krka.

### **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 Krka
- decreased sex drive (*libido*), this may continue after you stop taking Dutasteride Krka
- difficulty with ejaculation, such as a decrease in the amount of semen released during sex, this may continue after you stop taking Dutasteride Krka
- 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):

- depression
- pain and swelling in your testicles.

### **Reporting of 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:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Dutasteride Krka**

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 and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Keep the blister in the outer carton in order to protect from light.

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 Krka contains**

- The active substance is dutasteride. Each soft capsule contains 0.5 mg dutasteride.
- The other ingredients are: monocaprylate propylene glycol type II and butylhydroxytoluene (E321) in the capsule contents and gelatin, glycerol and titanium dioxide (E171) in the capsule shell. See section 2: “Dutasteride Krka contains propylene glycol”.

**What Dutasteride Krka looks like and contents of the pack**

Dutasteride Krka soft capsules (capsules) are oblong soft gelatin capsules (approximately 16.5 x 6.5 mm) of light yellow colour, filled with transparent liquid.

Dutasteride Krka is available in boxes of 10, 30, 50, 60 or 90 soft capsules in Transparent Triplex (PVC-PE-PVDC)/Aluminium blisters.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

**Manufacturer**

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia  
 Laboratorios León Farma, SA, Polígono Industrial Navatejera, C/La Vallina s/n, Villaquilambre-León, 24008 Navatejera (León), Spain

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Denmark, Belgium, Finland, Ireland	Dutasteride Krka
Bulgaria	Дутрис
Estonia, Spain, Latvia, Croatia,	Dutryst
Portugal	Dutasterida Krka

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