

# XUPROS DUTASTERIDE SOFT GELATIN CAPSULES 0.5 MG

Dutasteride Soft Gelatin Capsules (0.5 mg)

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## What XUPROS is used for

XUPROS 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 XUPROS 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 (*acute urinary retention*). This requires immediate medical treatment. In some situations, surgery is necessary to remove or reduce the size of the prostate gland.

XUPROS 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.

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

## Before you use XUPROS

### - *When you must not use it*

Do not take this medicine if:

- if you are allergic to dutasteride, other 5-alpha reductase inhibitors, or to any of the other ingredients of this medicine.
- 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.

### - *Before you start to use it*

Talk to your doctor before taking XUPROS.

- 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 XUPROS.

- Women, children and adolescents must not handle leaking XUPROS 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 XUPROS. 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.

- XUPROS 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 XUPROS. Men taking XUPROS should have their PSA tested regularly.

- In a clinical study of men at increased risk of prostate cancer, men taking XUPROS had a serious form of prostate cancer more often than men who did not take XUPROS. The effect of XUPROS on this serious form of prostate cancer is not clear.

- XUPROS 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 XUPROS.

## *Pregnancy and Lactation*

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

## - *Taking other medicines*

Tell your doctor if you are taking or have recently taken:

Some medicines can react with XUPROS 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 XUPROS may need to be reduced.

## How to use XUPROS

Always take XUPROS 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 use**

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.

**- When to use it**

XUPROS can be taken with or without food.

**- How long to use it**

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

**- If you forget to use it**

Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

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

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

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

**While you are using XUPROS**

**- Things you must do**

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

Some medicines can react with XUPROS and may make it more likely that you'll have side-effects.

Use a condom during sexual intercourse. Dutasteride has been found in the semen of men taking Dutasteride capsules. If your partner is or may be pregnant, you must avoid exposing her to your semen.

XUPROS has been shown to reduce sperm count, semen volume and sperm movement. Therefore, male fertility may be reduced.

**- Things you must not do**

**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.

Contact your doctor for advice if a pregnant woman has come into contact with dutasteride.

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**

**Driving and using machines**

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

**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 XUPROS.

**Common side effects**

*These may affect up to 1 in 10 men taking XUPROS:*

- not able to achieve or maintain an erection (*impotence*), this may continue after you stop taking XUPROS.

- decreased sex drive (*libido*), this may continue after you stop taking XUPROS.
- difficulty with ejaculation, such as a decrease in the amount of semen released during sex, this may continue after you stop taking XUPROS.
- breast enlargement or tenderness (*gynecomastia*)
- dizziness when taken with tamsulosin.

**Uncommon side effects**

*These may affect up to 1 in 100 men taking XUPROS:*

- 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.
- 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](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

**Storage and Disposal of XUPROS**

**- 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.

**Product Description**

- *What it looks like*

Colorless, 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 0.5 mg dutasteride.

- Inactive Ingredients

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

- *MAL number*

MAL xxxxxxxxxxxx

**Manufacturer**

MEGA LIFESCIENCES Public Company Limited

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**Product Registration Holder**

MEGA LIFESCIENCES SDN. BHD.

B-28-02, The Ascent, Paradigm.

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23<sup>rd</sup> January 2025

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