

Prostasafe®

PROSTASAFE 5 mg film-coated tablets (finasteride)

This medicine is for use in men only

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.

In this leaflet:

1. What **Prostasafe** is and what it is used for
2. What you need to know before you take **Prostasafe**
3. How to take **Prostasafe**
4. Possible side effects
5. How to store **Prostasafe**
6. Further information

1. What **Prostasafe** is and what it is used for

This medicine contains an active substance called finasteride, which belongs to a group of medicines called '5-alpha reductase inhibitors'. It acts by reducing the size of the prostate gland in men.

Finasteride is used for:

- The treatment and control of benign (i.e. non cancerous) enlargement of the prostate (benign prostatic hyperplasia, BPH).
- It causes shrinkage of the enlarged prostate, improves urinary flow and symptoms caused by BPH and reduces the risk of sudden acute urinary retention and the need for surgery.

2. What you need to know before you take **Prostasafe**

Do not take this medicine:

- if you are allergic to finasteride or any of the other ingredients of this medicine.
- if you are a woman (see also under 'Pregnancy and breast-feeding').
- if you are a child.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- If you have a large amount of residual urine in your bladder after urinating and/or severely reduced urinary flow, you should be closely monitored for narrowing of the urinary tract.
- If you have impaired liver function, the level of finasteride in your blood may be increased.
- If your partner is pregnant or may be pregnant, you should avoid exposing her to your semen which could contain a tiny amount of the drug.
- If you have a PSA test (test used to detect prostate cancer), tell your doctor that you are taking finasteride.

Finasteride can affect the blood levels of the substance being tested, PSA.

Tell your doctor if any of the above applies to you now or in the past.

You should promptly report to your doctor any changes in your breast tissue such as lumps, pain, enlargement of the breast tissue or nipple discharge as these may be signs of a serious condition, such as breast cancer.

Take special care with **Prostasafe**

Prostasafe can affect a blood test called PSA. If you have a PSA test done, tell your doctor that you are taking **Prostasafe**.

BPH is not cancer and does not lead to cancer, but the two conditions can be present at the same time. Before starting you on **Prostasafe**, it is likely that your doctor will perform some simple tests to check whether you have prostate cancer.

Your doctor will evaluate your symptoms and their possible causes. Talk to your doctor if you have any questions. Before starting treatment with **Prostasafe**, the treating physician should

exclude that the difficulty of you to pass urine is due to trilobular growth pattern of the prostate.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This medicine does not usually affect other medicines.

Taking with food and drink

This medicine can be taken with or without food.

Pregnancy and breast-feeding

Finasteride is only intended for men.

Women who are or may potentially be pregnant should not handle finasteride tablets especially if broken or crushed. If finasteride is absorbed through the skin or taken by mouth by pregnant women with a male foetus, the child may be born with malformed genital organs.

When the patient's sexual partner is or may become pregnant, the patient should either avoid exposure of his partner to semen (e.g. by use of a condom) or discontinue treatment with finasteride.

If a woman who is pregnant comes into contact with Finasteride, a doctor should be consulted. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

This medicine is not likely to affect you being able to drive, use tools or machines.

This medicine contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take **Prostasafe**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose is one tablet daily (equivalent to 5 mg finasteride).
- The film-coated tablets can either be taken on an empty stomach or with a meal. The film coated tablets should be swallowed whole and should not be divided or crushed.
- Although early improvement may be seen, treatment for at least six months may be necessary to assess whether a beneficial response has been achieved.

• Your doctor may prescribe Finasteride along with another medicine (called doxazosin) to help control your BPH.

• Your doctor will tell you how long you should continue to take this medicine. Do not interrupt treatment early as the symptoms may come back.

Patients with impaired liver function

There is no experience of the use of finasteride in patients with impaired liver function (see also 'Warnings and precautions').

Patients with impaired kidney function

No dosage adjustment is required. The use of Finasteride in patients who have to undergo haemodialysis has not been investigated yet.

Elderly patients

No dosage adjustment is required. Please speak to your doctor or pharmacist if you feel that the effects of this medicine is too strong or too weak.

If you take **Prostasafe** more than you should

If you have taken more tablets than you were told to, or if someone else has taken any tablets, contact accident and emergency department of your nearest hospital. Take any left over tablets or empty box with you for easier identification.

If you forget to take **Prostasafe**

If you forget to take a dose of this medicine, you can take it as soon as you remember unless it is time for the next dose, in which case you should continue with your medication as prescribed. Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

Do not stop taking this medicine unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Stop taking this medicine, and see your doctor straightaway, if you notice any signs of allergic reaction which may include:

- Skin rashes, itching, or lumps under your skin.
- Swelling of lips, face, tongue or throat.
- Difficulty in swallowing.
- Breathing difficulties.

The side effects have usually been temporary with continued treatment or disappeared when treatment is stopped.

You should promptly report to your doctor any changes in your breast tissue such as lumps, pain, enlargement or nipple discharge as these may be signs of a serious condition, such as breast cancer.

Common (may affect up to 1 in 10 people)

- impotence (an inability to have an erection),
- less desire to have sex.
- problems with ejaculation such as a decrease in the amount of semen released.

Uncommon (may affect up to 1 in 100 people)

- rash,
- breast swelling or tenderness.
- problems with ejaculation.

Frequency unknown (cannot be estimated from the available data)

- hypersensitivity reactions, including swelling of the lips, tongue, throat and face.
- pain in the testicles.
- fast heart beat.
- depression.

• persistent difficulty having an erection after discontinuation of treatment.

• persistent decrease in sex drive after discontinuation of treatment.

• persistent problems with ejaculation after discontinuation of treatment.

• infertility has been reported in men who took finasteride for long time and had other risk factors that may affect fertility. Normalisation or improvement of seminal quality has been reported after discontinuation of finasteride.

Long-term clinical studies about the effect of finasteride on fertility in men have not been conducted.

• elevated liver enzymes.

5. How to store **Prostasafe**

• 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 label after EXP. The expiry date refers to the last day of that month.

• Do not store 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.

6. Further Information

What **prostasafe** contains

- The active substance is finasteride.
- The other ingredients are: lactose, microcrystalline cellulose, povidone, sodium starch glycolate, magnesium stearate, hypromellose, titanium dioxide, triacetin, FD&C blue, indigo carmine aluminum lake and carmine.

What **prostasafe** looks like and contents of the pack

Prostasafe (5 mg) tablets are blue, round tablet.

Prostasafe is supplied in pack containing 3 blisters, each blister contains 10 tablets.

Marketing Authorization holder and manufacturer:

Azal Pharma

Tele: (+249)185322770

Fax: (+249)155118855

E-mail: azal@azalpharma.com

Website: www.azalpharma.com

To report any Side effect
National Medicines and Poisons Board (NMPB)
Fax: (+249)183522263
E-mail: inf@nmpb.gov.sd
Website: www.nmpb.gov.sd

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consultation your doctor.
- Keep medication out of reach of children.

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Azal pharma.
Khartoum - Sudan

31016

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نوع الخط: Times New Roman
حجم الخط: 5
رقم البانتون: 5473 U
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