PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ZEDRAST 0,5 mg soft capsules

Dutasteride

Sugar free.

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ZEDRAST has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ZEDRAST is and what it is used for

2. What you need to know before you take ZEDRAST

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1. What ZEDRAST is and what it is used for

ZEDRAST contains the active substance dutasteride that belongs to a group of medicines called 5 alpha-reductase inhibitors. ZEDRAST is used in men to treat prostate enlargement, also referred to

as benign prostatic hyperplasia (BPH). BPH is an increased growth of the prostate gland and is caused by your body producing too much of a hormone called dihydrotestosterone.

ZEDRAST decreases your body's production of dihydrotestosterone, thereby reducing the size of your enlarged prostate and relieving accompanying symptoms, such as difficulty passing urine and an urge to urinate more often than usual. By doing this, ZEDRAST lowers the need for surgery in men with enlarged prostates.

2. What you need to know before you take ZEDRAST

Do not take ZEDRAST

- If you are hypersensitive (allergic) to dutasteride or any of the other ingredients of ZEDRAST listed in section 6 of this leaflet.
- If you are a woman.
- If you are a child or adolescent younger than 18 years old.
- If you have severe liver disease.

Warnings and precautions

Take special care with ZEDRAST

- Before you start and while you are taking ZEDRAST, your doctor may examine and evaluate you for any signs of prostate cancer. During your treatment with ZEDRAST, your doctor may also monitor the prostate specific antigen (PSA) levels in your blood, which is used to indicate the health of your prostate.
- ZEDRAST may change the levels of PSA in your blood. If you are due to have your PSA levels tested, tell your doctor that you are taking ZEDRAST.
- Women and children should not handle leaking ZEDRAST capsules, because it can be absorbed through the skin. In the event of contact with a leaking capsule, the contact area of the skin should immediately be washed with soap and water. ZEDRAST should not be chewed or opened as contact with the capsule may cause irritation of the mucous membrane

in the mouth and throat.

Tell your doctor:

- If you are taking any medicine to treat your enlarged prostate.
- If you have been diagnosed with prostate cancer or have a history of prostate cancer in your family.
- If you suffer from any heart problems.
- If you notice any changes in your breast tissue (such as lumps, tenderness or nipple discharge).
- If you have liver problems.

Children and adolescents

ZEDRAST should not be taken by children and adolescents younger than 18 years.

Other medicines and ZEDRAST

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist before you take ZEDRAST if you use:

- Verapamil or diltiazem (used to treat high blood pressure and heart problems).
- Ritonavir or indinavir (used to treat human immunodeficiency syndrome (HIV) or acquired immunodeficiency syndrome (AIDS)).
- Itraconazole or oral ketoconazole (used to treat fungal infections).

If you are taking colestyramine (used to lower cholesterol) and you are prescribed ZEDRAST, take the medicines at least one hour apart.

You should also tell any doctor who is prescribing a new medicine for you that you are taking

ZEDRAST.

ZEDRAST with food and drink

ZEDRAST can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking ZEDRAST.

Women should not take ZEDRAST. **Women who are pregnant or may be pregnant should not handle any 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.

If you are taking ZEDRAST and your partner is or may possibly be pregnant, you should use a condom during sexual intercourse to avoid exposing her to your semen. Dutasteride has been found in the semen of men taking ZEDRAST. Dutasteride, as in ZEDRAST may 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 ZEDRAST capsule.

ZEDRAST has been shown to reduce sperm count, semen volume and sperm movement and may reduce fertility in male patients.
ZEDRAST has been shown to reduce sex drive.

Driving and using machines

Your ability to drive and use machines is unlikely to be affected by ZEDRAST. However, ZEDRAST can cause dizziness, mainly when taken in combination with an alpha-one blocker. If you are taking ZEDRAST and an alpha-blocker, do not drive or operate machinery unless you are feeling well.

ZEDRAST contains preservatives

ZEDRAST contains methyl hydroxybenzoate and propyl hydroxybenzoate as preservatives, which may cause allergic reactions (possibly delayed).

3. How to take ZEDRAST

Do not share medicines prescribed for you with any other person.
Always take ZEDRAST exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is 1 capsule (0,5 mg) once a day.
Your doctor will tell you how long your treatment with ZEDRAST will last.
If you have the impression that the effect of ZEDRAST is too strong or too weak, tell your doctor or pharmacist.
The capsules should be swallowed whole. Do not chew or open the capsule. Contact with the contents of the capsule may cause irritation in your mouth, throat or oesophagus (food pipe).
ZEDRAST is a long-term treatment. Some men may notice an early improvement in their symptoms. However, most may need to continue treatment for up to 6 months to see if ZEDRAST helps them.
ZEDRAST may be taken with or without food.

If you take more ZEDRAST than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ZEDRAST

If you forget to take a dose, take it as soon as you remember unless it is nearly time to take your next dose. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

ZEDRAST can have side effects.

Not all side effects reported for ZEDRAST are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZEDRAST, please consult your health care provider for advice.

If any of the following happens, stop taking ZEDRAST and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ZEDRAST. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Changes in the way your heart beats, irregular heartbeat or a sudden, rapid heartbeat.
- Chest pain or discomfort.
- Shortness of breath, rapid breathing, unexplained wheezing and persistent coughing.

- Changes in your breast tissue, such as tenderness, lumps or discharge from the nipple.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Swelling and pain in your testicles.
- Difficulty getting or maintaining an erection.
- Changes in ejaculation or a decrease in your semen volume.
- Changes in your sexual desire.
- Breast disorders (including breast tenderness and breast enlargement).

Less frequent side effects:

- Dizziness (especially when taken with an alpha-1 blocker).

The following side effects have been reported with unknown frequency:

- Feeling depressed.
- Hair loss (temporary).
- Abnormal growth of hair on your body.
- Pain and swelling of testicles.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ZEDRAST.

5. How to store ZEDRAST

- Store at or below 25 °C.
- Keep the blister strip in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ZEDRAST contains

The active substance in ZEDRAST is dutasteride.

Each capsule contains 0,5 mg dutasteride.

The other ingredients in ZEDRAST are butylated hydroxytoluene, ferric oxide yellow (colourant), gelatine, glycerol, glycerol monocaprylocaprate, titanium dioxide (colourant).

Contains preservatives: 0,2 % *m/m* methyl hydroxybenzoate and 0,2 % *m/m* propyl hydroxybenzoate.

What ZEDRAST looks like and contents of the pack

Opaque, yellow, oblong shaped soft gelatine capsules containing a clear, colourless to slightly yellowish oily liquid.

ZEDRAST is packed in aluminium-aluminium blister strips containing 6 soft gelatine capsules, packed in an outer container.

Pack size: 6

OR

Opaque PVC/PVDC and aluminium blister strips containing 10 soft gelatine capsules, packed in an outer container.

Pack sizes: 10 and 30.

Holder of certificate of registration

Zydus Healthcare SA (Pty) Ltd

Southdowns Office Park

Building A, Second Floor

22 Karee Street

Centurion 0157

South Africa

Tel: 012 748 6400

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Access to the corresponding Professional Information

The Professional Information is accessible at https://www.zydus.co.za/ or may be requested by contacting 012 748 6400.