

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Dutasteride Teva

Soft capsules

Each soft capsule contains: Dutasteride 0.5 mg

For a list of inactive ingredients, see section 6 – “Further Information”.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is intended for men only.

1. WHAT IS THE MEDICINE INTENDED FOR?

- For treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH).
- To reduce the risk of acute urinary retention (AUR) and surgery in patients with moderate to severe symptoms of benign prostatic hyperplasia (BPH).

Dutasteride Teva is used to treat men with an enlarged prostate gland (benign prostatic hyperplasia) – a noncancerous tumor of the prostate gland, caused by overproduction of a hormone called dihydrotestosterone. Enlargement of the prostate gland can lead to urinary system problems, such as difficulty in passing urine and frequent need to go to the bathroom. Likewise, it may slow and weaken the urine flow. If left untreated, there is risk that your urine flow will become fully blocked (*acute urinary retention*). This condition requires immediate medical treatment. In certain cases, there is a need to surgically remove or reduce the size of the prostate. Dutasteride Teva reduces the production of dihydrotestosterone, thereby helping reduce the size of the prostate and relieving symptoms. This will reduce the risk of acute urinary retention and the need for surgery.

Dutasteride Teva can also be used with another medicine called tamsulosin (used to treat symptoms of an enlarged prostate gland).

Therapeutic group

5-alpha-reductase enzyme inhibitors.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- **You are sensitive (allergic) to dutasteride, other 5-alpha-reductase inhibitors or to any of the additional ingredients contained in the medicine as detailed in section 6 – “Further Information”.**
- **You have a severe liver disease.**

Do not take the medicine and tell your doctor if you think any of these apply to you.

The medicine is intended for men only! Do not use this preparation in women, children or adolescents.

Special warnings regarding use of the medicine

Discuss with your doctor before taking Dutasteride Teva.

- **Be sure that your doctor knows if you have liver problems.** If you had any ailment that affected the liver, you may need to undergo additional tests when taking Dutasteride Teva.

- **Women, children and adolescents** must avoid contact with leaking capsules of Dutasteride Teva, since the active ingredient can be absorbed through the skin. If any contact is made with the skin, **wash the contact area immediately** with soap and water.

- **Use a condom during sexual contact.** Dutasteride has been found in sperm of men taking Dutasteride Teva. If your partner is pregnant or may be pregnant, you must avoid exposing her to your sperm, since dutasteride may affect the normal development of a male fetus. Dutasteride has been found to lower sperm counts, semen fluid volume and sperm motility. This may reduce your fertility.

- **Dutasteride Teva affects the PSA (prostate-specific antigen) blood test,** which is sometimes used to detect prostate cancer. Your doctor should be aware of this effect but can still use this test to detect prostate cancer. If you undergo a PSA blood test, tell your doctor that you are taking Dutasteride Teva. **Men taking Dutasteride Teva need to check their PSA regularly.**

- In a clinical study in men with increased risk of prostate cancer, men who took Dutasteride Teva developed a **severe degree of prostate cancer more frequently** than men who did not take Dutasteride Teva. The effect of Dutasteride Teva on the severity of prostate cancer is unclear.

- **Dutasteride Teva may cause breast enlargement or tenderness.** If this becomes bothersome, or if you notice **lumps in the breast or discharge from the nipple,** talk to your doctor about these changes, as they may be signs of a severe medical problem, such as breast cancer.

Refer to your doctor or pharmacist if you have any questions with regards to taking Dutasteride Teva.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, if you are taking certain medicines that may react with Dutasteride Teva, which may increase the likelihood that you will have side effects. These medicines include:

- **Verapamil or diltiazem** (for high blood pressure)
- **Ritonavir or indinavir** (for infection with HIV – human immunodeficiency virus)
- **Itraconazole or ketoconazole** (for fungal infection)
- **Nefazodone** (antidepressant)
- **Alpha blockers** (to treat an enlarged prostate gland or high blood pressure).

Tell your doctor if you are taking any of these medicines. It may be necessary to reduce the dosage of Dutasteride Teva that you are taking.

Use of the medicine and food

Dutasteride Teva can be taken with or without food.

Pregnancy, breastfeeding and fertility

Women who are pregnant (or who may be pregnant) must avoid contact with leaking capsules. Dutasteride is absorbed through the skin and may affect the normal development of a male fetus. This risk is increased during the first 16 weeks of pregnancy.

Use a condom during sexual contact. Dutasteride has been found in the seminal fluid of men taking Dutasteride Teva. If your partner is pregnant or may be pregnant, you must avoid exposing her to your sperm. Dutasteride Teva has been found

to lower sperm counts, semen fluid volume and sperm motility. Therefore, male fertility may be reduced.

Tell your doctor if a pregnant woman has come into contact with dutasteride.

Driving and operating machinery

It is unlikely that Dutasteride Teva will affect your ability to drive or operate machinery.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally one capsule (0.5 mg) taken once a day.

Treatment with Dutasteride Teva is long-term. Some men will notice an early improvement in their symptoms. However, others will have to take Dutasteride Teva for 6 months or more before the medicine begins to have an effect. Continue taking Dutasteride Teva for as long as the doctor tells you to.

Do not exceed the recommended dose.

Swallow the capsule whole with water. Do not chew and do not open and disperse the contents of the capsule. Contact with the content of the capsule may cause pain in your mouth or throat.

If you accidentally took a higher dosage, consult your doctor or pharmacist.

If you took an overdose, or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine

at the designated time, do not take a double dose. Take the next dose at the regular time and consult the doctor.

Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. It is possible that it may take 6 months or longer until you feel the effect of the medicine.

If you do not take the medicine regularly, monitoring of your PSA levels may be affected.

Do not take medicines in the dark!

Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Dutasteride Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Allergic reaction

The signs of an allergic reaction can include:

- **Skin rash** (which can be itchy)
- **Urticaria** (like a nettle rash)
- **Swelling of the eyelids, face, lips, arms or legs.**

Tell your doctor immediately if you notice any of these symptoms **and stop using Dutasteride Teva.**

Additional side effects

Common side effects

Effects that may occur in up to one in 10 men taking Dutasteride Teva:

- Inability to achieve or maintain an erection (*impotence*). The effect can persist after you stop taking Dutasteride Teva
- Reduced sexual drive (*libido*). The effect can persist after you stop taking Dutasteride Teva
- Ejaculation disturbances such as reduced seminal discharge during sexual intercourse. The effect can persist after you stop taking Dutasteride Teva
- Breast enlargement or tenderness in the breast (*gynecomastia*)
- Dizziness, when taken with tamsulosin.

Uncommon side effects

Effects that may occur in up to one in 100 men taking Dutasteride Teva:

- Heart failure (the heart becomes less effective in pumping blood through the body. You may have symptoms such as shortness of breath, extreme tiredness and swelling of your ankles and legs)
- Hair loss (usually from the body) or hair growth.

Side effects of unknown frequency

The frequency cannot be estimated from existing data:

- Depression
- Testicular pain and swelling.

If a side effect occurs, if any of the side effects worsen, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Store the medicine below 25°C. Keep in the original package to protect from light.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

glycerol monocaprylocaprate, gelatin (bovine, monocaprylocaprate), glycerol (E422), titanium dioxide (E171), iron oxide yellow (E172), butylhydroxytoluene (E321), medium chain triglycerides, purified water.

What the medicine looks like and the contents of the package

Dutasteride Teva soft Capsules are oblong and opaque yellow capsules, that contain a colorless or slightly yellow oily liquid or soft mass.

Dutasteride Teva is packaged in packages of 10 or 30 soft capsules in trays (blisters).

Not all package sizes may be marketed.

Name of Manufacturer and License Holder and Address:

Teva Israel Ltd., 124 Devorah Hanevia St., Tel Aviv 6944020.

The leaflet was revised in May 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

160.48.35344