

Package leaflet: Information for the patient

Dutasteride Teva 0.5 mg Soft Capsules

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 Teva is and what it is used for
2. What you need to know before you take Dutasteride Teva
3. How to take Dutasteride Teva
4. Possible side effects
5. How to store Dutasteride Teva
6. Contents of the pack and other information

1. What Dutasteride Teva is and what it is used for

Dutasteride Teva contains the active substance dutasteride. Dutasteride Teva belongs to a group of medicines called 5-alpha reductase inhibitors.

Dutasteride Teva 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.

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 Teva 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 Teva 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 Teva

Do not take Dutasteride Teva

- If you are allergic to dutasteride, 5-alpha reductase inhibitors or any of the other ingredients of this medicine (listed in section 6),
- If you have a severe liver disease.

Inform your doctor if you think any of these apply to you.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Dutasteride Teva

Take special care with Dutasteride Teva

- 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.
- **Your doctor must be aware about your liver problems before using this medicine.** If you have had any illness affecting your liver, you may need regular monitoring while you are taking Dutasteride Teva.
- **Women, children and adolescents** must not handle leaking Dutasteride Teva 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. 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 Teva 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 Teva. **Men taking Dutasteride Teva should have their PSA tested regularly.**
- Dutasteride Teva **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.
- In a clinical study of men at increased risk of prostate cancer, men taking dutasteride had a **serious form of prostate cancer more often** than men who did not take dutasteride. The effect of dutasteride on this serious form of prostate cancer is not clear.

Contact your doctor or pharmacist if you have any questions about taking Dutasteride Teva.

Other medicines and Dutasteride Teva

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, as these can interact with Dutasteride Teva and increase the risk of side-effects. Your dose of Dutasteride Teva may need to be reduced. 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).

Dutasteride Teva with food and drink

Dutasteride Teva can be taken with or without food.

Pregnancy, breast-feeding and fertility

Women who are pregnant (or may be) must avoid any contact with 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 Teva. If your partner is or may be pregnant, you must avoid exposing her to your semen.

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

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

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

3. How to take Dutasteride Teva

Always take this medicine exactly as your doctor or pharmacist has told you. 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.

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.

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

If you take more Dutasteride Teva than you should

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

If you forget to take Dutasteride Teva

Do not take a double dose to make up for a forgotten capsule. Just take your next dose at the usual time and then continue as earlier.

If you stop taking Dutasteride Teva

Don't stop taking Dutasteride Teva 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.**

Stop using Dutasteride Teva and contact your doctor immediately if you get any of these symptoms.

Common: may affect up to 1 in 10 men

- impotence (not able to achieve or maintain an erection) this may continue after you stop taking Dutasteride Teva
- decreased sex drive (libido) this may continue after you stop taking Dutasteride Teva
- difficulty with ejaculation this may continue after you stop taking Dutasteride Teva
- 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

- depressed mood
- pain and swelling in your testicles

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store Dutasteride Teva

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

Do not store above 30°C. Store in the original package in order to protect from light.

Do not use this medicine if you notice visible signs of deterioration.

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 Teva contains

- The active substance is dutasteride. Each soft capsule contains 0.5 mg of dutasteride
- The other ingredients are butylhydroxytoluene (E321) and glycerol monocaprylocaprate, medium chain triglycerides, purified water.
- The capsule shell contains gelatine (160 Bloom), glycerol (E422), titanium dioxide (E171) and yellow Iron Oxide (E172).

What Dutasteride Teva looks like and contents of the pack

Dutasteride Teva 0.5 mg soft capsules are size 6, oblong, yellow, opaque capsules filled with colourless or slightly yellow, oily liquid or soft mass, without printing.

They are available in packs of 10, 28, 30, 50, 60, 90 and 100.

10 (blister of: 2 x 5 capsules, 1 x 10 capsules) /carton

28 (blister of: 2 x 14 capsules, 4 x 7 capsules, 7 x 4 capsules)/carton

30 (blister of: 3 x 10 capsules, 6 x 5 capsules) /carton

50 (blister of: 5 x 10 capsules, 10 x 5 capsules)/carton

60 (blister of: 6 x 10 capsules, 12 x 5 capsules)/carton

90 (blister of: 9 x 10 capsules, 18 x 5 capsules) /carton

100 (blister of: 10 x 10 capsules 5 x 20 capsules)/carton

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Teva Pharma B.V.

Swensweg 5

2031GA Haarlem

Netherlands

Manufacturers:

TEVA Pharmaceutical Works Private Limited Company, Pallagi út 13, 4042 Debrecen, Hungary.

Pharmachemie B.V., Swensweg 5, 2031 GA Haarlem, The Netherlands

Teva Czech Industries s.r.o, Ostravska 29, c.p. 305, 74770 Opava-Komarov, Czech Republic.

Merckle GmbH, Ludwig-Merckle-Straße 3, 89143 Blaubeuren, Germany.

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

Denmark: Dutasteride Teva

Estonia: Dutasteride Teva

Finland: Dutasteride ratiopharm 0,5 mg pehmeä kapseli

France: Dutasteride Teva 0,5 mg capsule molle

Iceland: Dutasteride ratiopharm 0,5 mg mjúkt hylki

Italy: Dutasteride Teva 0.5 mg capsule molli

Ireland: Dutasteride Teva 0,5 mg Soft Capsules

Latvia: Dutasteride Teva 0,5 mg mīkstās kapsulas

Lithania: Dutasteride Teva 0,5 mg minkštos kapsulės

Netherlands: Dutasteride Teva 0,5 mg, zachte capsules

Poland: Dutasteride Teva, 0,5 mg, kapsułki miękkie

Portugal: Dutasterida Teva

Slovenia: Dutasterid Teva 0,5 mg mehke kapsule

Spain: Dutasterida Teva 0,5 mg cápsulas blandas EFG

United Kingdom: Dutasteride 0.5 mg Soft Capsules

This leaflet was last revised in May 2021.