Package leaflet:
Information for the user

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

1. What Dutasteride is and what it is used for

Dutasteride 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.

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. Dutasteride 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 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

Do not take Dutasteride
- **if you're allergic to dutasteride, other 5-alpha reductase inhibitors** or to any of the other ingredients of this medicine (listed in section 6).
- **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.
This medicine is for men only. It must not be taken by women, children or adolescents.

Warnings and precautions
Talk to your doctor or pharmacist before taking Dutasteride.
- **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 Dutasteride.
- **Women, children and adolescents** must not handle leaking Dutasteride 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 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. **Men taking Dutasteride should have their PSA tested regularly**.
- 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.
- **Dutasteride 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 Dutasteride.

Other medicines and Dutasteride
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:

Some medicines can react with Dutasteride 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 ketaconazole** (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 Dutasteride may need to be reduced.

Dutasteride with food and drink
Dutasteride can be taken with or without food.

Pregnancy, breast-feeding and fertility
If your partner is pregnant, breast-feeding, or think they may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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.

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.

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

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

Driving and using machines
Dutasteride is unlikely to affect your ability to drive or operate machinery.

3. How to take Dutasteride

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.

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

If you take more Dutasteride than you should
Contact your doctor or pharmacist for advice if you take too many Dutasteride capsules.

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

If you stop taking Dutasteride:
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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

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.**

Contact your doctor immediately if you get any of these symptoms, and **stop using Dutasteride.**

Common: (may affect up to 1 in 10 men taking Dutasteride)
- not able to achieve or maintain an erection (impotence), this may continue after you stop taking Dutasteride
- decreased sex drive (libido), this may continue after you stop taking Dutasteride
- difficulty with ejaculation, such as a decrease in the amount of semen released during sex, this may continue after you stop taking Dutasteride.
- breast enlargement or tenderness (gynecomastia)
- dizziness when taken with tamsulosin.

Uncommon: (may affect up to 1 in 100 men taking Dutasteride)
- 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)
- depression
- pain and swelling in your testicles.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Dutasteride

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, carton, blister or bottle after EXP. The expiry date refers to the last day of that month.

Store below 30 °C.
Store in the original package in order to protect from moisture.

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 contains

- The active substance is dutasteride. Each soft, capsule contains 0.5 mg dutasteride.
- The other ingredients are:
  Capsule contents: glycerol monocaprylocaprate (Type I) and butylated hydroxy toluene (E321).
  Capsule shell: gelatin, glycerol, titanium dioxide (E171) and iron oxide yellow (E172).

What Dutasteride looks like and contents of the pack

Capsule, soft.

Dull yellow, opaque, oblong shaped, size '6' soft gelatin capsule containing clear colorless to pale yellow viscous oil.

Dutasteride capsules are available in blister packs and HDPE bottles.

Pack sizes:
Blister packs: 10, 30, 50, 60 and 90 capsules
HDPE packs: 500 capsules

Not all pack sizes may be marketed.

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