

## Package leaflet: Information for the user

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

#### **1. What Quedute is and what it is used for**

The active ingredient is dutasteride. It belongs to a group of medicines called 5-alpha reductase inhibitors.

**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.

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 Quedute**

##### **Do not take Quedute**

- if you're allergic to dutasteride, other 5-alpha reductase inhibitors, soya, peanut or to any of the other ingredients of this medicine (listed in section 6)
- if you have a severe liver disease
- if you are a child or adolescent.

**Tell your doctor** if you think any of these apply to you.

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

#### **Warnings and precautions**

Talk to your doctor before taking Quedute.

- 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.
- **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 Quedute**

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 ketoconazole** (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.

### **Quedute with food and drink**

Dutasteride can be taken with or without food.

### **Pregnancy, breast-feeding and fertility**

Women must not take dutasteride.

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

**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.

### **Driving and using machines**

Quedute is unlikely to affect your ability to drive or operate machinery.

### **Quedute contains soya lecithin**

This medicine contains lecithin from soya, which may contain soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

## **3. How to take Quedute**

**Always take this medicine exactly as your doctor has told you.** Check with your doctor or pharmacist if you are not sure. If you do not take it regularly the monitoring of your PSA levels may be affected.

### **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 Quedute than you should**

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

### **If you forget to take Quedute**

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 Quedute**

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.

**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**

**Contact you doctor immediately** if you get any of these symptoms, and **stop using dutasteride**

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.**

### **Common side effects**

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, \*this may continue after you stop taking dutasteride

- breast enlargement or tenderness (gynecomastia)
- dizziness when taken with tamsulosin.

### **Uncommon side effects**

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 side effects**

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 HPR

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Quedute**

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

Do not store Quedute above 30°C.

Store in the original container 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 Quedute contains**

The active substance is dutasteride.

Each soft capsule contains 0.5 mg dutasteride.

The other ingredients are:

- inside the capsule: glycerol monocaprylocaprate (type I) butylhydroxytoluene (E321).
- capsule shell: gelatine, glycerol, titanium dioxide (E171), iron oxide yellow (E172), triglycerides (medium chain), lecithin (may contain soya oil) (E322) and purified water.

### **What Quedute looks like and contents of the pack**

Quedute soft capsules are size 6, oblong opaque and yellow, soft gelatin capsules containing an oily and yellowish liquid. They are available in packs of 10, 30, 60 and 90 capsules. Not all pack sizes may be marketed.

Soft capsules dimensions are:  $19 \pm 0.8$  mm x  $6.9 \pm 0.4$  mm.

### **Marketing Authorisation Holder and Manufacturers**

#### **Marketing Authorisation Holder**

Rowex Ltd., Bantry, Co. Cork, Ireland.

**Manufacturers**

Galenicum Health S.L., Avda. Cornellá 144, 7<sup>o</sup>-1<sup>a</sup>, Edificio Lekla, Esplugues de Llobregat, 08950 Barcelona, Spain.

Cyndeia Pharma, S.L., Polígono Industrial Emiliano Revilla Sanz, Avenida de Ágreda, 31 Olvega, 42110, Soria, Spain.

Pharmadox Healthcare, Ltd., KW20A Kordin Industrial Park, Paola , PLA 3000, Malta.

LEK Pharmaceuticals d.d., Verovškova ulica 57, 1526 Ljubljana, Slovenia.

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

<b>Malta:</b>	Quedute 0,5 mg soft capsules
<b>Belgium:</b>	Dutasteride Sandoz 0,5 mg zachte capsule
<b>Bulgaria:</b>	Кведут 0,5 mg меки капсули
<b>Cyprus:</b>	Dutasteride Sandoz 0,5 mg μαλακές κάψουλες
<b>Denmark:</b>	Dutasterid Hexal
<b>France:</b>	Dutasteride Sandoz 0,5 mg capsule molle
<b>Ireland:</b>	Quedute 0,5 mg soft capsules
<b>Italy:</b>	Dutasteride Sandoz Gmbh
<b>Lithuania:</b>	Quedute 0,5 mg minkštosios kapsulės
<b>Latvia:</b>	Quedute 0,5 mg mīkstās kapsulas
<b>Luxemburg:</b>	Quedute 0,5 mg capsule molle
<b>Netherlands:</b>	Dutasteride Sandoz 0,5 mg, capsules, zacht
<b>Portugal:</b>	Dutasterida Sandoz 0,5 mg cápsulas moles
<b>Romania:</b>	Avaterid 0,5 mg capsule moi
<b>Slovenia:</b>	Testadart 0,5 mg mehke kapsule
<b>Spain:</b>	Dutasterida Sandoz 0,5 mg cápsulas blandas EFG

**This leaflet was last revised in 03/2017.**