

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dutrozen 0.5 mg / 0.4 mg hard capsules

dutasteride/tamsulosin hydrochloride

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 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 Dutrozen is and what it is used for
2. What you need to know before you take Dutrozen
3. How to take Dutrozen
4. Possible side effects
5. How to store Dutrozen
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1. What Dutrozen is and what it is used for

Dutrozen 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.

Dutrozen is a combination of 2 different medicines called dutasteride and tamsulosin. Dutasteride belongs to a group of medicines called 5-alpha reductase inhibitors and tamsulosin belongs to a group of medicines called alpha-blockers.

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. Sometimes surgery is necessary to remove or reduce the size of the prostate gland.

Dutasteride lowers the production of a hormone called 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. Tamsulosin acts by relaxing the muscles in your prostate gland, making it easier to pass urine and rapidly improving your symptoms.

2. What you need to know before you take Dutrozen

Do not take Dutrozen if you

- are a **woman** (because **this medicine is for men only**).
- are a **child or adolescent less than 18 years old**.
- are **allergic to dutasteride, other 5-alpha reductase inhibitors, tamsulosin, soya, peanut (soya lecithin) or to any of the other ingredients of this medicine** (listed in section 6).
- have **low blood pressure** which makes you feel dizzy, lightheaded or faint (orthostatic hypotension).
- 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.

Warnings and precautions

Talk to your doctor before taking Dutrozen

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 Dutrozen.
- **Make sure your doctor knows if you have severe problems with your kidney.**
- **Cataract (cloudy lens) surgery.** If you are going to have surgery to remove a cataract, your doctor may ask you to stop taking Dutrozen for a while before your operation. Tell your eye specialist before your operation that you are taking Dutrozen or tamsulosin (or have previously taken it). Your specialist will need to take appropriate precautions to help prevent complications during your operation.
- **Women, children and adolescents** must not handle leaking Dutrozen 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 Dutrozen. 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.
- **Dutrozen 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 Dutrozen. **Men taking Dutrozen 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.
- **Dutrozen 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 Dutrozen.

Other medicines and Dutrozen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Dutrozen with these medicines:

- Other alpha-blockers (for enlarged prostate or high blood pressure).

Dutrozen is not recommended with these medicines:

- Ketoconazole (used to treat fungal infections).

Some medicines can react with Dutrozen and may make it more likely that you will have side effects. These medicines include:

- PDE5 inhibitors (used to help achieve or maintain an erection) such as vardenafil, sildenafil citrate and tadalafil.
- Verapamil or diltiazem (for high blood pressure).
- Ritonavir or indinavir (for HIV).
- Itraconazole or ketoconazole (for fungal infections).
- Nefazodone (an antidepressant).
- Cimetidine (for stomach ulcers).
- Warfarin (for blood clotting).
- Erythromycin (an antibiotic used to treat infections).
- Paroxetine (an antidepressant).
- Terbinafine (used to treat fungal infections).
- Diclofenac (used to treat pain and inflammation).

Tell your doctor if you are taking any of these medicines.

Dutrozen with food and drink

Dutrozen should be taken 30 minutes after the same meal each day.

Pregnancy, breast-feeding and fertility

Dutrozen must not be taken by women.

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 Dutrozen. If your partner is or may be pregnant, you must avoid exposing her to your semen.

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

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

Driving and using machines

Dutrozen makes some people feel dizzy, so it may affect your ability to drive or operate machinery safely. Don't drive or operate machinery if you are affected in this way.

Dutrozen contains sodium and propylene glycol monocaprylate and soya lecithin

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially "sodium-free".

Dutrozen contains 299.46 mg propylene glycol monocaprylate (equivalent to 112.80 mg propylene glycol) in each capsule and traces of propylene glycol in the black ink.

This medicine may contain traces of soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product (see section Do not take Dutrozen).

3. How to take Dutrozen

Always take this medicine exactly as your doctor or pharmacist has told you to. 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 1 capsule taken once a day, 30 minutes after the same meal each day.

How to take

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.

If you take more Dutrozen than you should

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

If you forget to take Dutrozen

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 Dutrozen

Do not stop taking Dutrozen without talking to your doctor first.

If you have any further questions on the use of this product, 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.
- Contact your doctor immediately if you get any of these symptoms and stop using Dutrozen.

Dizziness, light-headedness and fainting

Dutrozen can cause dizziness, lightheadedness and on rare occasions fainting. Take care when moving from a lying down or sitting position to sitting or standing, particularly if you wake up in the night, until you know how this medicine affects you. If you feel dizzy or lightheaded at any time during treatment, sit or lie down until the symptoms pass.

Serious skin reactions

The signs of serious skin reactions can include:

- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).

Contact a doctor immediately if you get these symptoms and stop using Dutrozen.

Other side effects

Common (may affect up to 1 in 10 people):

- Impotence (not able to achieve or maintain an erection)*.
- Decreased sex drive (libido)*.
- Difficulty with ejaculation, such as a decrease in the amount of semen released during sex*.
- Breast enlargement or tenderness (gynecomastia).
- Dizziness.

* In a small number of people some of these events may continue after you stop taking Dutrozen.

Uncommon (may affect up to 1 in 100 people):

- 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).
- Low blood pressure on standing.
- Fast heartbeat (palpitations).
- Constipation, diarrhoea, vomiting, feeling sick (nausea).
- Weakness or loss of strength.
- Headache.
- Itchy, blocked or runny nose (rhinitis).
- Skin rash, hives, itching.
- Hair loss (usually from the body) or hair growth.

Rare (may affect up to 1 in 1,000 people):

- Swelling of the eyelids, face, lips, arms or legs (angioedema).
- Faintness

Very rare (may affect up to 1 in 10,000 people):

- Persistent painful erection of the penis (priapism).
- Serious skin reactions (Stevens-Johnson syndrome)

Other side effects have occurred in a small number of men, but their exact frequency is **not known** (the frequency cannot be estimated from available data):

- Abnormal or fast heartbeat (arrhythmia or tachycardia or atrial fibrillation).
- Shortness of breath (dyspnoea).
- Depression.
- Pain and swelling in your testicles.
- Nose bleeds.
- Severe skin rash.
- Changes in vision (blurred vision or visual impairment).
- Dry mouth.

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 Yellow Card Scheme at: 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 Dutrozen

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

Store below 30 °C. Use within 90 days after first opening.

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 Dutrozen contains

- The active substances are dutasteride (0.5 mg) and tamsulosin hydrochloride (0.4 mg, equivalent to 0.367 mg tamsulosin).

• The other ingredients are:

Dutasteride soft capsules: Propylene glycol monocaprylate, type II; Gelatine; Glycerol; Titanium dioxide (E171); Butylhydroxytoluene (E321); Triglycerides (medium chain)*; Soya lecithin (may contain soya oil)*.

* potential traces from manufacturing process

Tamsulosin modified released pellets: Cellulose microcrystalline; Metacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30 per cent (contains also sodium laurylsulfate and polysorbate 80); Dibutyl sebacate; Silica, colloidal hydrated; Polysorbate 80; Calcium stearate.

Hard gelatine capsules: Gelatine; Titanium dioxide (E171); Red iron oxide (E172); Yellow iron oxide (E172); Black iron oxide (E172).

Black ink: Propylene glycol (E1520); Potassium hydroxide; Ammonia solution, concentrated; Black iron oxide (E172); Shellac.

What Dutrozen looks like and contents of the pack

Dutrozen is oblong hard gelatine capsules of 24.2 x 7.7 mm, with brown body and beige cap printed with C001 in black ink. Each capsule contains:

- One oblong soft gelatine capsule of dutasteride (approximately 16.5x6.5 mm) of light yellow colour, filled with transparent liquid.
- Approximately 183.8 mg of modified release tamsulosin pellets of white to off white colour.

Dutrozen is packed in white HDPE bottle with silica gel desiccant contained in the white polypropylene cap.

7, 30, 90 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, United Kingdom

The Manufacturer is LABORATORIOS LEON FARMA, S.A., C/La Vallina s/n, Polígono Industrial Navatejera, Villaquilambre, León 24008 Spain

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