

GSK Logo

Package Leaflet: Information for the User

COMBODART® 0.5 mg/0.4 mg hard capsules **dutasteride/tamsulosin hydrochloride**

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- **If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

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1 What Combodart is and what it is used for

Combodart 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.

Combodart is a combination of two 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 Before you take Combodart

Do not take Combodart

- **if you're allergic** (*hypersensitive*) **to dutasteride, other 5-alpha reductase inhibitors, tamsulosin, soya, peanut** or to any of the other ingredients of Combodart.
- **if you have low blood pressure** which makes you feel dizzy, lightheaded or faint (*orthostatic hypotension*).
- **if you have a severe liver disease.**
 - ➔ **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.

Take special care with Combodart

- 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 Combodart.
- **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 Combodart for a while before your operation. Tell your eye specialist before your operation that you are taking Combodart 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 Combodart 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 Combodart. 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.
- **Combodart 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 Combodart. **Men taking Combodart 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.
- **Combodart 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 Combodart.

Taking other medicines

Tell your doctor if you're taking or have recently taken any other medicines. This includes any medicines you've bought without a prescription.

Don't take Combodart with these medicines:

- **other alpha-blockers** (for enlarged prostate or high blood pressure)

Combodart is not recommended with these medicines:

- **ketoconazole** (used to treat fungal infections)

Some medicines can react with Combodart and may make it more likely that you'll 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) in combination with **paroxetine** (an antidepressant) or in combination with **terbinafine** (used to treat fungal infections)

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

Food and drink with Combodart

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

Pregnancy and breast-feeding

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

Combodart 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 Combodart.

Driving and using machines

Combodart 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.

Important information about some of the ingredients of Combodart

This medicine contains the colouring agent sunset yellow (E110) which may cause allergic reactions.

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 Combodart

Always take Combodart exactly as your doctor 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 usual dose is one 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 too much Combodart

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

If you forget to take Combodart

Don't take extra capsules to make up for a missed dose. Just take your next dose at the usual time.

Don't stop Combodart without advice

Don't stop taking Combodart 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, Combodart 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 Combodart.**

Dizziness, lightheadedness and fainting

Combodart 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 Combodart.**

Common side effects

These may affect up to 1 in 10 men taking Combodart:

- impotence (not able to achieve or maintain an erection)*
- decreased sex drive (*libido*)*
- difficulty with ejaculation*
- breast enlargement or tenderness (*gynecomastia*)
- dizziness.

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

Uncommon side effects

These 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.)
- 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 side effects

These may affect up to 1 in 1,000 men

- swelling of the eyelids, face, lips, arms or legs (*angioedema*)
- fainting.

Very rare side effects

These may affect up to 1 in 10,000 men

- persistent painful erection of the penis (*priapism*).
- serious skin reactions (*Stevens-Johnson syndrome*).
➔ **If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

Not known side effects

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.

5 How to store Combodart

Keep out of the sight and reach of children.

Don't use Combodart after the expiry date which is stated on the carton and the bottle. The expiry date refers to the last day of that month.

Don't store Combodart above 30°C.

If you have any unwanted Combodart capsules, don't dispose of them in waste water or household rubbish. Take them back to your pharmacist, who will dispose of them in a way that won't harm the environment.

6 Further information

What Combodart contains

The active substances are dutasteride and tamsulosin hydrochloride. Each capsule contains 0.5 mg dutasteride and 0.4 mg tamsulosin hydrochloride.

The other ingredients are:

- hard capsule shell: hypromellose, carrageenan (E407), potassium chloride, titanium dioxide (E171), iron oxide red (E172), sunset yellow (E110), carnauba wax, maize starch.
- inside the hard capsule: mono-di-glycerides of caprylic/capric acid and butylhydroxytoluene (E321), gelatin, glycerol, titanium dioxide (E171), iron oxide yellow (E172), triglycerides (medium chain), lecithin (may contain soya oil), cellulose, microcrystalline, methacrylic acid - ethyl acrylate copolymer (containing polysorbate 80 and sodium laurilsulfate), talc, triethyl citrate.
- black print ink (SW-9010 or SW-9008): shellac, propylene glycol, iron oxide black (E172), potassium hydroxide (in Black Ink SW-9008 only).

What Combodart looks like and contents of the pack

This medicine is an oblong hard capsule with a brown body and an orange cap printed with GS 7CZ in black ink. They are available in packs of 7, 30 and 90 capsules. Not all pack sizes may be marketed.

Marketing authorisation holder

GlaxoSmithKline UK Limited, Stockley Park West, Uxbridge, Middlesex UB11 1BT

Manufacturer

Catalent Germany Schorndorf GmbH, Steinbeisstrasse 2, 73614 Schorndorf, Germany

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name Combodart

Reference number 19494/0046

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