Package leaflet: Information for the patient

Combodart® 0.5mg/0.4mg Hard Capsules

(dutasteride/tamsulosin hydrochloride)

Your medicine is available using the name Combodart® 0.5mg/0.4mg Hard Capsules but will be referred to as Combodart throughout the leaflet.

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. Do not pass it on to others. It may harm them, even if their symptoms 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 Combodart is and what it is used for
2. What you need to know before you take Combodart
3. How to take Combodart
4. Possible side effects
5. How to store Combodart
6. Contents of the pack and other information

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. What you need to know before you take Combodart

Do not take Combodart:

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

Warnings and precautions

Talk to your doctor before taking 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.

Other medicines and Combodart

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

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)
- **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.

Combodart with food and drink

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

Pregnancy, breast-feeding and fertility

Combodart **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 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

Combodart contains the colouring agent yellow orange S (E110) which may cause allergic reactions.

Combodart contains soy lecithin (may contain soybean 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 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 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 more Combodart than you should

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

If you forget to take Combodart

Do not take a double dose to make up for a forgotten 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, 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 Combodart.**

Dizziness, light-headedness and fainting

Combodart can cause dizziness, light-headedness 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, 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 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*).

Other side effects
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 Combodart

- **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 and the bottle. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- If your doctor decides to stop your treatment, return any leftover medicine to your pharmacist. Only keep the medicine if your doctor tells you to.
- If the medicine become discoloured or show any other signs of deterioration, you should consult your pharmacist who will advise you what to do.
- 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 Combodart contains
The active substances are dutasteride and tamsulosin hydrochloride.
Each capsule contains 0.5mg dutasteride and 0.4mg tamsulosin hydrochloride.

The other ingredients are:
- Hard capsule shell: hypromellose, carrageenan (E407), potassium chloride, titanium dioxide (E171), red iron oxide (E172), yellow orange S (E110), carnauba wax and corn starch.
- Inside the hard capsule: mono-di-glycerides of caprylic/capric acid, butylhydroxytoluene (E321), gelatin, glycerol, titanium dioxide (E171), yellow iron oxide (E172), medium chain triglycerides, soy lecithin (may contain soybean oil), microcrystalline cellulose, copolymer of methacrylic acid and ethyl acrylate co-polymer (containing polysorbate 80 and sodium lauryl sulfate), talc and triethyl citrate.
- Black print ink (SW-9010 or SW-9008): shellac, propylene glycol, black iron oxide (E172), potassium hydroxide (in black ink SW-9008 only).

What Combodart looks like and contents of the pack
Combodart is a hard, oblong capsule with a brown body and an orange cap printed with GS 7CZ in black ink.

Your medicine is available in a bottle containing 30 capsules.

Manufacturer
Manufactured by: Catalent Germany Schorndorf GmbH, Steinbeisstrasse 2, 73614 Schorndorf, Germany.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: Doncaster Pharma Limited, Crompton Road, Doncaster, DN2 4PW, UK.

PL: 56830/0036 POM

Leaflet revision & issue date (Ref): 10.08.22

Trademark Owner: GlaxoSmithKline Group of Companies.

Blind or partially sighted? Is this leaflet hard to see or read? Call 01302 365000 (Regulatory)

Please be ready to give the following information:
Product name: Combodart 0.5mg/0.4mg hard capsules
Reference No: 56830/0036