

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed according to a physician's prescription only

Duodart

capsules

Each capsule contains 0.5 mg dutasteride and 0.4 mg tamsulosin hydrochloride.

For a list of the inactive and allergenic ingredients in the preparation, see section 2 “Important information about some ingredients of the medicine” and section 6 “Additional information”.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is intended for men only.

1. WHAT IS THE MEDICINE INTENDED FOR?

- Treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH).
- Reduction in the risk of acute urinary retention (AUR) and surgery in patients with moderate to severe symptoms of BPH.

Therapeutic group: Duodart 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.

Duodart 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.

Growth of the prostate 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 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 the prostate gland, making it easier to pass urine and rapidly improving symptoms.

2. BEFORE USING THE MEDICINE

Do not use Duodart:

- **if you are sensitive (allergic) to the active ingredients dutasteride and tamsulosin hydrochloride, to other 5-alpha reductase inhibitors, soya, peanuts** or to any of the additional ingredients contained in the medicine (as listed in section 6).
 - **in women** (as the medicine is intended for men only).
 - **in children or adolescents under the age of 18.**
 - **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 do not take the medicine until you have checked with the physician.

Special warnings regarding the use of the medicine

Talk to the physician before you take Duodart.

- 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 the physician knows if you have liver problems.** If you have had any illness that affected your liver, you may need some additional check-ups while you are taking Duodart.
- **Make sure the physician knows if you have severe problems with your kidney.**
- **Cataract (cloudy lens) surgery.** If you are going to have surgery to remove a cataract, the physician may ask you to stop taking Duodart for a while before the operation. Tell the ophthalmologist before the operation that you are taking Duodart or tamsulosin (or have previously taken these medicines). The ophthalmologist will need to take appropriate precautions to help prevent complications during the operation.
- **Women, children and adolescents** must avoid contact with leaking Duodart 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 Duodart. 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 fetus. Dutasteride has been shown to decrease sperm count, semen volume and sperm motility. This could reduce your fertility.
- **Duodart affects a blood test for PSA** (*prostate-specific antigen*), which is

sometimes used to detect prostate cancer. The physician 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 the physician that you are taking Duodart. **Men taking Duodart should have their PSA tested regularly.**

- In a clinical study of men at increased risk of prostate cancer, men who took dutasteride developed a **severe 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.
- **Duodart may cause breast enlargement and tenderness.** If this becomes troublesome, or if you notice **breast lumps** or **nipple discharge** you should talk to the physician about these changes as these may be signs of a serious condition, such as breast cancer.
- **Contact the physician or pharmacist** if you have any questions about taking Duodart.

Children and adolescents

Do not use Duodart in children and adolescents under the age of 18.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist. Especially if you are taking the following medicines.

Do not take Duodart with these medicines:

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

Duodart is not recommended with these medicines:

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

Some medicines can react with Duodart 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 - human immunodeficiency virus)
- **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 the physician** if you are taking any of these medicines.

Using the medicine and food

Take Duodart 30 minutes after the same meal each day.

Pregnancy, breast-feeding and fertility

Duodart is prohibited for use in women.

Pregnancy

Women who are pregnant (or may be pregnant) must avoid contact with leaking capsules. Dutasteride is absorbed through the skin and can affect the normal development of a male fetus. This risk is increased during the first 16 weeks of pregnancy.

Use a condom during sexual intercourse. Dutasteride has been found in the semen of men taking Duodart. If your partner is or may be pregnant, you must avoid exposing her to your semen.

→ **Tell the physician** if a pregnant woman has come into contact with Duodart.

Fertility

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

Driving and using machines

Duodart causes dizziness in some people, so it may affect your ability to drive or operate machinery safely.

→ **Do not drive or operate machinery** if you are affected in this way.

Important information about some ingredients of the medicine

Duodart contains the colouring agent Sunset yellow (E110), which is also called FD&C yellow 6, which may cause an allergic reaction.

Duodart contains lecithin from soya. If you are allergic to peanuts or soya, do not use this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this preparation according to the physician's instructions. Check with the physician or the pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined only by the physician.

The usual dosage is generally one capsule taken once a day, 30 minutes after the same meal each day.

Do not exceed the recommended dose.

Swallow the capsule whole with water. Do not chew and do not open and disperse the contents of the capsule since contact with the contents of the capsule may make mouth or throat sore.

Instructions for opening the bottle package - to remove the cap, press down, while

simultaneously twisting to the left (turning counterclockwise).

Instructions for closing the bottle package - place cap on top of open end and twist to the right (turning clockwise) until it locks.

If you accidentally have taken a higher dosage

You should consult the physician or pharmacist.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine

Do not take a double dose to compensate for the forgotten dose. Take the next dose at the usual time.

If you stop taking the medicine

Persist with the treatment as recommended by the physician. Even if there is an improvement in your health, do not stop the treatment with the medicine without consulting the physician.

If you do not take the medicine regularly, the monitoring of your PSA levels may be affected.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Duodart may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Allergic reaction

The signs of an allergic reaction can include:

- **skin rash** (which can be itchy)
- **hives** (like a nettle rash)
- **swelling of the eyelids, face, lips, arms or legs.**

→ **Tell the physician immediately** if you get any of these symptoms, and **stop using Duodart.**

Dizziness, lightheadedness and fainting

Duodart can cause dizziness, lightheadedness and on rare occasions fainting. Take care when moving from a lying down or sitting position to a sitting or standing position, 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 the physician immediately** if you notice any of these symptoms and **stop using Duodart**.

Additional side effects

Common side effects

These may occur in up to **1 in 10** men taking Duodart:

- 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*
- tenderness or enlargement of the breast (*gynecomastia*)
- dizziness.

* In a small number of people some of these effects may continue after discontinuation of Duodart.

Uncommon side effects

These may occur in up to **1 in 100** men taking Duodart:

- 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 ankles and legs)
- low blood pressure on standing
- fast heartbeat (*palpitations*)
- constipation, diarrhoea, vomiting, nausea
- weakness or lack 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 occur in up to **1 in 1,000** men taking Duodart:

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

Very rare side effects

These may occur in up to **1 in 10,000** men taking Duodart:

- persistent painful erection
- serious skin reactions (*Stevens-Johnson syndrome*).

Side effects of unknown frequency

Other side effects have occurred in a small number of men, but their 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
- depression
- pain and swelling in the testicles
- nosebleed
- severe skin rash
- vision changes (blurred or impaired vision)
- dry mouth.

→ **If a side effect occurs, if any of the side effects get worse or when you suffer from a side effect that has not been mentioned in the leaflet, you should consult the physician.**

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Do not store above 30°C. Use within 3 months from first opening and no later than the expiry date of the product.
- Do not discard medicines via wastewater or household waste. Consult with the pharmacist on how to throw away medicines that are not in use. These steps will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredients the medicine also contains:
 - Hard capsule shell: hypromellose, iron oxide red (E172), titanium dioxide (E171), water purified, carrageenan (E407), potassium chloride, FD&C yellow 6 [Sunset yellow (E110)], carnauba wax, maize starch.
 - Inside the hard capsule: mono-di-glycerides of caprylic/capric acid (MDC) and butylhydroxytoluene (BHT), gelatin, glycerol, titanium dioxide (E171), ferric oxide (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, iron oxide black (E172), propylene glycol, potassium hydroxide (in Black Ink SW-9008 only).
- What does the medicine look like and what is the content of the package:
This medicine is an oblong, hard, brown and orange capsule on which GS 7CZ is printed in black ink. The capsules are available in packs of 7, 30 and 90 capsules. Not all pack sizes may be marketed.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Catalent Germany Schorndorf GmbH, Schorndorf, Germany.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 146-34-33278
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