PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DUODART Capsules

Dutasteride 0,5 mg and tamsulosin hydrochloride 0,4 mg

Sugar-free

Read all of this leaflet carefully before you start taking DUODART.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor , pharmacist, nurse or other healthcare provider.
- DUODART has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. What DUODART is and what it is used for:

DUODART capsules are 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 who have difficulty to pass urine and/or with a weak urine flow associated with an enlarged prostate (benign prostatic hyperplasia) - a non-cancerous growth of the prostate gland.

2. What you need to know before you take DUODART:

Do not take DUODART:

- if you are allergic (hypersensitive) to dutasteride, tamsulosin or to any of the other ingredients of DUODART (see section 6. Contents of the pack and other information), or to other medicines known as 5-alpha reductase inhibitors.
- if you are female or under 18 years of age. DUODART is for adult men only
- if you have a history of orthostatic hypotension (this is a form of low blood pressure (feel very dizzy) that happens when you stand from lying or sitting down
- if you have severe liver disease.

If any of these apply to you, do not take DUODART until you have checked with your doctor.

Warnings and precautions:

Take special care with DUODART:

- In clinical studies with dutasteride, some patients took dutasteride and a type of medicine called an alpha-blocker. The patients taking dutasteride and an alpha-blocker had heart failure more often than patients taking only dutasteride or only an alpha-blocker. (Heart failure means your heart does not pump blood as well as it should.)

  If you are taking DUODART (which is a combination of dutasteride and an alpha-blocker), talk to your doctor about this and other possible side effects.
- If you have liver disease, check with your doctor that DUODART is suitable for you. You may need extra check-ups while you are taking DUODART.

- If you are going to have cataract (cloudy lens) surgery. Tell your doctor or eye specialist before your operation that you are taking or have previously taken DUODART. They may ask you to temporarily stop taking DUODART before your operation.
- Women, children and adolescents must not handle 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.
- Men taking DUODART may be at an increased risk of developing a form of prostate cancer. Men taking DUODART should have their PSA (prostate specific antigen) measure 6 months after starting treatment and regularly thereafter. DUODART will reduce the amount of PSA measured in your blood. You could still be at risk for prostate cancer even though your PSA is lower. Your doctor can still use PSA level to help detect prostate cancer, by comparing your test results each time you have a PSA test.
- DUODART 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 e.g. breast cancer.

Conditions you need to look out for:

DUODART can cause dizziness and light-headedness. See POSSIBLE SIDE EFFECTS - Conditions you need to look out for.

Other medicines and DUODART:

Always tell your healthcare professional if you are taking other medicine. (This includes complementary or traditional medicines.)

Do not take DUODART with these medicines:

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

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

- PDE5 inhibitors (used to help achieve/maintain an erection) such as vardenafil, sidenafil and tadalafil
- cimetidine (for stomach ulcers)
- warfarin (for blood clotting)
- erythromycin (an antiobiotic used to treat infections)
- paroxetine (an antidepressant)
- terbinafine and ketoconazole (used to treat fungal infections).

Tell your doctor or pharmacist if you are taking any of these.

Pregnancy, breastfeeding and fertility:

You must not take DUODART if you are female.

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 the contents of a DUODART capsule.

Male Fertility: DUODART has been shown to reduce sperm count, semen volume and sperm movement. However, it is not clear if male fertility is affected by DUODART.

Driving and using machines:

DUODART can make some people feel dizzy. Do not drive or operate machinery unless you are feeling well.

DUODART contains

The active substances are dutasteride and tamsulosin.

Each capsule contains 0,5 mg dutasteride and 0,4 mg tamsulosin hydrochloride.

The inactive ingredients include mono-di-glycerides of caprylic/capric acid, butylhydroxytoluene, gelatin, glycerol, titanium dioxide, purified water, microcrystalline cellulose, methacrylic acid - ethyl acrylate copolymer, talc, triethyl citrate, carrageenan, potassium chloride, hypromellose, triglycerides, medium chain, lecithin, carnauba wax, maize starch, yellow iron oxide, red iron oxide, FD&C Yellow 6.

DUODART contains:

The capsule shell contains the colouring agent FD&C yellow 6, which may cause allergic reactions.

3. How to take DUODART:

Do not share medicines prescribed for you with any other person.

Always take DUODART exactly as your doctor has told you. Check with your doctor or pharmacist if you're not sure.

The usual dose of DUODART is one capsule taken once a day.

Swallow your DUODART capsules whole with some water, approximately 30 minutes after the same meal each day. Do not chew or open the capsules. Contact with the contents of the capsules may make your mouth or throat sore.

If you take more DUODART than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is availble, contact the nearest hospital or poison centre.

If you forget to take DUODART:

Do not take extra capsules to make up for a missed dose**.** Just take your next dose at the usual time.

If you stop taking DUODART:

Take DUODART for as long as your doctor recommends. Do not stop taking DUODART without talking to your doctor first.

4. Possible side effects:

DUODART can have side effects.

Not all side effects reported for DUODART are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DUODART, please consult your doctor, pharmacist or other healthcare professional.

Conditions you need to look out for:

- **Dizziness and light-headedness**:

  DUODART can cause dizziness, light-headedness and sometimes 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 DUODART affects you. If you feel dizzy or light-headed at any time during treatment, sit or lie down until the symptoms pass.

- **Allergic reactions:**

  DUODART can cause allergic reactions. If any of the following happens, stop taking DUODART immediately or go to the causuality deparment at your nearest hospital:

  - raised and itchy rash (hives)
  - swelling, sometimes of the face or mouth (angioedema) causing difficulty in breathing
  - collapse.

  These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DUODART. You may need urgent medical attention or hospitalisation.

Frequent side effects include:

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

Less frequent side effects include:

- allergic reactions
- fast heartbeat (palpitations)
- constipation, diarrhoea, vomiting
- weakness or loss of strength (asthenia)
- low blood pressure on standing (postural hypotension)
- itchy, blocked or runny nose (rhinitis).

Other side effects:

- fainting
- hair loss (usually from the body) or hair growth
- persistent painful erection of the penis (priapism)
- depressed mood
- serious skin reactions e.g. Steven-Johnson syndrome
- pain and swelling in your testicles
- abnormal or fast heartbeat (atrial fibrillation) and shortness of breath
- nose bleeds (epistaxis)
- changes in vision

- dry mouth

Contact a doctor urgently if this happens to you. You may need to have treatment to avoid serious complications.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store DUODART:

Store all medicines out of reach of children.

Store at or below 25°C.

Keep the container well closed.

Do not take DUODART after the expiry date shown on the pack.

Return any unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What DUODART looks like and contents of the pack:

DUODART capsules are oblong hard-shell capsules with a brown body and an orange cap, printed with 'GS 7CZ' on one side in black ink. Each capsule contains an oblong, dull yellow soft gelatin capsule and white to off-white pellets.

7, 30 or 90 capsules will be packed into opaque, white high-density polyethylene (HDPE) bottles with polypropylene child-resistant closures with induction-seal liners.

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

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