Approved Patient Information Leaflet for Medicines for Human Use

PRODART 0,5 mg

SCHEDULING STATUS: S4

PRODART 0,5 mg soft gelatin capsules

Dutasteride

Sugar free

Read all of this leaflet carefully before you start taking PRODART

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PRODART 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.
- 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 PRODART is and what it is used for

PRODART 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.

The active ingredient is dutasteride. It belongs to a group of medicines called 5-alpha reductase inhibitors. PRODART decreases the hormone dihydrotestosterone and thereby decreases the enlargement of the prostate.

2. What you need to know before you take PRODART

Do not take PRODART

- if you are hypersensitive (allergic) to dutasteride or any of the other ingredients of this PRODART (listed in section 6),
- if you are female, a child or an adolescent.

Do not take PRODART and tell your doctor if any of these apply to you.

Warnings and precautions

Take special care with PRODART

- Women, children and adolescents must not handle leaking PRODART 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.
- PRODART 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 PRODART. Men taking PRODART should have their PSA tested regularly.

- In two studies, incidence of heart failure (heart problems which can cause shortness of breath or ankle swelling), were slightly higher in patients taking the combination of dutasteride and an alpha-blocker, such as tamsulosin, than patients not taking the combination. However, other available data for dutasteride or alpha-blockers, do not support a conclusion of increased risk of heart failure.
- PRODART 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.
- 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 PRODART. Inform you doctor if while taking PRODART you experience severe tiredness, pain in the upper right part of your abdomen or notice yellowing of your skin or eyes.

Children and adolescents

PRODART should not be taken by children and adolescents.

Other medicines and PRODART

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines can interact with PRODART and may make it more likely that you can have side-effects as it may increase PRODART concentrations in your blood. These medicines include:

- verapamil or diltiazem (for high blood pressure)
- ritonavir or indinavir (for HIV)
- itraconazole or ketoconazole (for fungal infections)
- nefazodone (an antidepressant)

There were no observed reactions between PRODART and the following medicines:

- warfarin (prevents blood clots)
- diazepam (an antidepressant)
- phenytoin (an anticonvulsant)
- tamsulosin and terazosin (used to treat enlarged prostate)
- digoxin (used to treat heart failure)
- cholestyramine (used to treat high cholesterol)

PRODART with food, drink and alcohol

PRODART can be taken with or without food.

If any of the above apply to you, tell your doctor before taking PRODART, because the effect of PRODART may be increased. Your doctor will decide, if you should be treated with this medicine and if you should be kept under closer observation.

If your doctor thinks that you are at increased risk of developing stomach or bowel ulcers, he may also use a preventative ulcer treatment.

Pregnancy and breastfeeding and fertility

Do not take PRODART if you are pregnant or breastfeeding. Women who are pregnant (or may be) must not handle leaking capsules. PRODART is absorbed through the skin and can affect the normal development of a baby.

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

If your partner is pregnant or breastfeeding, think she may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

PRODART is unlikely to affect your ability to drive or operate machinery.

It is not always possible to predict to what extent PRODART may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PRODART affects them.

3. How to take PRODART

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

Always take PRODART exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose is one capsule (0,5 mg) taken once a day. Swallow the capsules whole with a glass of water. Do not chew or break open the capsule.

PRODART is a long-term treatment. Your doctor will tell you how long your treatment with PRODART will last. If you have the impression that the effect of PRODART is too strong or too weak, tell your doctor or pharmacist.

If you take more PRODART than you should

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

If you forget to take PRODART

Do not take a double dose to make up for forgotten individual doses. Just take your next dose at the usual time.

If you stop taking PRODART

Do not stop taking PRODART without talking to your doctor first, because PRODART prevents the progression of a serious condition.

4. Possible side effects

PRODART can have side effects.

Not all side effects reported for PRODART are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PRODART, please consult your health care provider for advice.

If any of the following happens, stop taking PRODART and tell your doctor immediately or go the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PRODART 0,5 mg. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go the casualty department at your nearest hospital if you notice any of the following side effects

Frequent side effects

- not being able to achieve or maintain an erection (impotence),
- decrease in your sex drive (libido),
- difficulty with ejaculation,
- breast enlargement or tenderness.

Frequency unknown

- allergic reactions, like rash, skin hives, swelling of the eyelids, face, arms or legs,
- feeling of depression or sadness,
- loss of body hair (alopecia) or excessive hair growth (hypertrichosis),
- pain and swelling of the male genitals (testicles).

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PRODART.

5. How to store PRODART

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Store in the original package.
- Do not use after the expiry date stated on the carton.
- Return all 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 PRODART contains

- The active substance is dutasteride. Each soft gel capsule contains 0,5 mg of dutasteride.
- The other ingredients are:

  Capsule contents: butylated hydroxy toluene, glycerol monocrylocaprate.

  Capsule shell: ferric oxide yellow, gelatin glycerine, glyceryl

monocaprylocaprate, purified water, titanium dioxide, printing ink (consisting of black iron oxide, hypromellose, isopropyl alcohol, purified water, propylene glycol).

What PRODART looks like and contents of the pack

PRODART 0,5 mg capsules are dull yellow, opaque colour, oblong shape, soft gelatin capsules containing clear transparent liquid imprinted with “DUTA 05” using black coloured edible ink.

Capsules are packed in white opaque PVC/PVDC and Aluminium foil blister strips of 10, which are further packed in printed cartons, in pack sizes of 30 or 100 capsules.

Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG

2193

South Africa

Tel: 0860287835

www.austell.co.za

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