

SCHEDULING STATUS: S4

DUTASTERIDE TAMSULOSIN ADCO 0,5 mg / 0,4 mg, hard capsules

Dutasteride / tamsulosin hydrochloride

Lecithin: each capsule contains traces of lecithin (may contain soya oil.)

Propylene glycol monocaprylate : each capsule contains 299,46 mg propylene glycol monocaprylate (equivalent to 112,80 mg propylene glycol) and traces of propylene glycol in the black ink.

Sodium laurylsulfate: each capsule contains 0,01 mg sodium.

Read all of this leaflet carefully before you start taking DUTASTERIDE TAMSULOSIN ADCO

- 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.
- DUTASTERIDE TAMSULOSIN ADCO 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 DUTASTERIDE TAMSULOSIN ADCO is and what it is used for
2. What you need to know before you take DUTASTERIDE TAMSULOSIN ADCO
3. How to take DUTASTERIDE TAMSULOSIN ADCO
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1. What DUTASTERIDE TAMSULOSIN ADCO is and what it is used for

DUTASTERIDE TAMSULOSIN ADCO 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.

DUTASTERIDE TAMSULOSIN ADCO 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 DUTASTERIDE TAMSULOSIN ADCO

Do not take DUTASTERIDE TAMSULOSIN ADCO:

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

Warnings and precautions

Take special care with DUTASTERIDE TAMSULOSIN ADCO:

- In some clinical studies, more patients taking dutasteride and another medicine called an alpha-blocker, like tamsulosin, experienced heart failure than patients taking dutasteride or an alpha blocker alone. Heart failure means your heart does not pump blood as well as it should.
- If you have had any illness affecting your liver, you may need some additional check-ups while you are taking DUTASTERIDE TAMSULOSIN ADCO.

- If you have severe kidney problems.
- DUTASTERIDE TAMSULOSIN ADCO may cause dizziness, as it can decrease your blood pressure. If you feel dizzy, sit or lie down, until you feel better.
- If you are going to have surgery to remove a cataract, your doctor may ask you to stop taking DUTASTERIDE TAMSULOSIN ADCO for a while before your operation. Tell your eye specialist before your operation that you are taking DUTASTERIDE TAMSULOSIN ADCO 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 DUTASTERIDE TAMSULOSIN ADCO 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.
- Dutasteride has been found in the semen of men taking DUTASTERIDE TAMSULOSIN ADCO. 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. You should therefore use a condom during sexual intercourse. Dutasteride has been shown to decrease sperm count, semen volume and sperm motility. This could reduce your fertility.
- DUTASTERIDE TAMSULOSIN ADCO 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 DUTASTERIDE TAMSULOSIN ADCO. Men taking DUTASTERIDE TAMSULOSIN ADCO 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.
- DUTASTERIDE TAMSULOSIN ADCO 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.

Children and adolescents

DUTASTERIDE TAMSULOSIN ADCO is not safe for the use in children and adolescents under the age of 18 years (see section 2, [What you need to know before you take DUTASTERIDE TAMSULOSIN ADCO]).

Other medicines and DUTASTERIDE TAMSULOSIN ADCO

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

Don't take DUTASTERIDE TAMSULOSIN ADCO with these medicines:

- other alpha blockers (for enlarged prostate or high blood pressure).
- ketoconazole (used to treat fungal infections).

Some medicines can react with DUTASTERIDE TAMSULOSIN ADCO 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 (medicine to treat high blood pressure).
- ritonavir or indinavir (medicine used in the treatment of HIV/AIDS).
- itraconazole or ketoconazole (medicines used to treat fungal infections).
- nefazodone (an antidepressant).
- cimetidine (for the treatment of stomach ulcers and heartburn).
- warfarin (medicine to treat blood clotting).
- paroxetine (an antidepressant).
- diclofenac (a pain and inflammation medicine).

DUTASTERIDE TAMSULOSIN ADCO with food and drink

DUTASTERIDE TAMSULOSIN ADCO should be taken 30 minutes after a meal at the same time each day.

Pregnancy and breastfeeding and fertility

DUTASTERIDE TAMSULOSIN ADCO must not be taken by woman.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking DUTASTERIDE TAMSULOSIN ADCO.

Women who are pregnant (or may be) must not handle leaking capsules.

Dutasteride as contained in DUTASTERIDE TAMSULOSIN ADCO 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 DUTASTERIDE TAMSULOSIN ADCO.

Use a condom during sexual intercourse.

Dutasteride has been found in the semen of men taking DUTASTERIDE TAMSULOSIN ADCO. If your partner is or may be pregnant, you must avoid exposing her to your semen.

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

Driving and using machines

DUTASTERIDE TAMSULOSIN ADCO 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.

It is not always possible to predict to what extent DUTASTERIDE TAMSULOSIN ADCO 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 DUTASTERIDE TAMSULOSIN ADCO affects them.

DUTASTERIDE TAMSULOSIN ADCO contains soya lecithin, propylene glycol monocaprylate and sodium

DUTASTERIDE TAMSULOSIN ADCO contains:

- Lecithin from soya, which may contain soya oil. If you are allergic to peanut or soya, do not use DUTASTERIDE TAMSULOSIN ADCO.
- 299,46 mg propylene glycol monocaprylate (equivalent to 112.80 mg propylene glycol) in each capsule and traces of propylene glycol in the black ink.
- Less than 1 mmol sodium (23 mg) per capsule, that is to say essentially "sodium-free".

3. How to take DUTASTERIDE TAMSULOSIN ADCO

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

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

The recommended dose is one capsule taken once a day, 30 minutes after a meal on the same time each day.

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.

Your doctor will tell you how long your treatment with DUTASTERIDE TAMSULOSIN ADCO will last. Do not stop treatment early without discussing it with your doctor. If you have the impression that the effect of DUTASTERIDE TAMSULOSIN ADCO is too strong or too weak, tell your doctor or pharmacist.

If you take more DUTASTERIDE TAMSULOSIN ADCO 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/ missed a dose of DUTASTERIDE TAMSULOSIN ADCO

Do not take a double dose to make up for forgotten individual doses.

If you stop taking DUTASTERIDE TAMSULOSIN ADCO

Don't stop taking DUTASTERIDE TAMSULOSIN ADCO without talking to your doctor first.

4. Possible side effects

DUTASTERIDE TAMSULOSIN ADCO can have side effects.

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

If any of the following happens, stop taking DUTASTERIDE TAMSULOSIN ADCO and tell your doctor immediately or go to 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.
- skin rash (which can be itchy).
- hives (swollen, pale red bumps).

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

Dizziness, light-headedness and fainting

DUTASTERIDE TAMSULOSIN ADCO 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 DUTASTERIDE TAMSULOSIN ADCO.

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

- 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).
- abnormal or fast heartbeat (arrhythmia or tachycardia or atrial fibrillation).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- 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 DUTASTERIDE TAMSULOSIN ADCO.

Less frequent side effects:

- low blood pressure on standing that may cause dizziness or fainting.
- (palpitations).
- constipation, diarrhoea, vomiting, feeling sick (nausea).
- weakness or loss of strength.
- headache.
- itchy, blocked or runny nose (rhinitis).
- persistent painful erection of the penis.
- weakness or lack of energy (asthenia).

Side effects of an unknown frequency:

- depression.
- nose bleeds.
- hair loss (usually from the body) or hair growth.
- pain and swelling of the testicles.
- changes in vision or blurred vision.

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. This includes any possible side effects not listed in this leaflet. 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 DUTASTERIDE TAMSULOSIN ADCO.

5. How to store DUTASTERIDE TAMSULOSIN ADCO

Store all medicines out of reach of children.

Store at or below 30 °C.

Keep the bottle tightly closed.

In addition, it should be used within 90 days of opening.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

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

Dutasteride is absorbed through the skin, therefore contact with leaking capsules must be avoided. If contact is made with leaking capsules, the contact area should be washed immediately with soap and water.

6. Contents of the pack and other information

What DUTASTERIDE TAMSULOSIN ADCO 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

Black iron oxide (E172)

Gelatin

Red iron oxide (E172)

Titanium dioxide (E171)

Yellow iron oxide (E172)

Contents in Dutasteride Soft Capsule

Butylhydroxytoluene (E321)

Propylene Glycol Monocaprylate, Type II

Soft Capsule Shell

Gelatin

Glycerol

Lecithin (may contain soya oil)

Titanium dioxide (E171)

Triglycerides (medium chain)

Tamsulosin Pellets

Calcium stearate

Dibutyl sebacate

Methacrylic acid - ethyl acrylate copolymer 1:1 dispersion 30 per cent

Microcrystalline cellulose

Polysorbate 80

Silica, colloidal hydrous

Black Ink

Black Iron Oxide (E172)

Potassium Hydroxide

Propylene Glycol

Shellac (E904)

Strong ammonia solution

What DUTASTERIDE TAMSULOSIN ADCO looks like and contents of the pack

Oblong hard gelatine capsule N° 0EL, of 24.2 mm x 7.7 mm approx, body of brown colour and cap of beige colour with black code C001 on the cap.

Each hard capsule contains:

- one oblong soft gelatine capsule of Dutasteride (approximately 16,5 x 6,5 mm) of light-yellow colour, filled with transparent liquid, and
- approximately 183,8 mg of modified release tamsulosin pellets with a white to off-white colour.

Hard capsules packed in a white, high density polyethylene (HDPE) bottle with silica gel desiccant contained in the cap.

7 hard capsules in 35 ml bottle.

30 hard capsules in 100 ml bottle.

90 hard capsules in 250 ml bottle.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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