

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ACTASVO 0,5 mg soft capsules

Dutasteride hydrochloride.

Sugar free

Read all of this leaflet carefully before you start taking ACTASVO

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

1. What ACTASVO is and what it is used for

ACTASVO is used to treat men with an enlarged prostate (benign prostatic hyperplasia). This is a noncancerous growth of the prostate gland, caused by producing too much of a hormone called dihydrotestosterone.



The active ingredient in ACTASVO is dutasteride. Dutasteride belongs to a group of medicines called 5-alpha reductase inhibitors.

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.

2. What you need to know before you take ACTASVO

Do not take ACTASVO:

- If you are allergic to dutasteride, other 5-alpha reductase inhibitors, soya, or to any of the other ingredients of this medicine (listed in [section 6](#)).
- 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 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

Take special care with ACTASVO:

- If the capsules are leaking. Women, children and adolescents must not handle leaking ACTASVO 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.

- 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 ACTASVO.
- You should have a digital rectal examination and other tests for prostate cancer before starting ACTASVO and periodically thereafter.
- ACTASVO affects the 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 ACTASVO. Men taking ACTASVO should have their PSA tested regularly.
- Men taking dutasteride, as in ACTASVO, may have a higher incidence of a serious form of prostate cancer than men who do not take dutasteride. The effect of dutasteride on this serious form of prostate cancer is not clear.
- ACTASVO may cause your breast to enlarge and become more tender. 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.
- More patients taking dutasteride together with another medicine called an alpha-blocker, like tamsulosin, may experience heart failure than patients taking only dutasteride or only an alpha-blocker. However, there is no conclusive evidence of this risk. Heart failure means your heart does not pump blood as well as it should.

Other medicines and ACTASVO

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



Some medicines can react with ACTASVO and may make it more likely that you have side effects. These medicines include:

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

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

Pregnancy, breastfeeding and fertility

ACTASVO 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.

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

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

Contact your medical practitioner for advice if a pregnant woman has come into contact with ACTASVO.

Driving and using machines

ACTASVO should not interfere with your ability to drive or operate machinery. However, it is not always possible to predict to what extent ACTASVO may interfere with your daily activities. Therefore, you should ensure that you do not engage in the above mentioned activities until you are aware of the measure to which ACTASVO affects you.



ACTASVO contains soya

ACTASVO contains lecithin from soya. Do not use ACTASVO if you are allergic to soya.

3. How to take ACTASVO

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

Always take ACTASVO exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

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

The recommended dose is one capsule taken once a day. ACTASVO can be taken with or without food.

Swallow the capsules whole with water. Do not chew or break open the capsule.

Your doctor will tell you how long your treatment with ACTASVO will last. Do not stop treatment because you feel better. ACTASVO is a long-term treatment, that is 6 months or longer before it begins to have an effect.

If you have the impression that the effect of ACTASVO is too strong or too weak, tell your doctor or pharmacist.

If you take more ACTASVO 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 a dose of ACTASVO

If you miss a dose, take it as soon as you remember. However, if it is time for your next dose, skip the missed dose and take only a single dose as usual. Do not take a double dose to



make up for a forgotten dose. Do not take more than the daily amount of ACTASVO that has been prescribed for you in one day.

4. Possible side effects

ACTASVO can have side effects.

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

Allergic reaction

If any of the following happens, stop taking ACTASVO 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.
- Rash or itching.

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

Tell your doctor if you notice any of the following:

Frequent side effects

- Not able to achieve or maintain an erection (Impotence)
- Decreased sex drive (libido)
- Difficulty with ejaculation, such as a decrease in the amount of semen released during sex
- Breast tenderness or breast enlargement

Less frequent side effects

- Hair loss (usually from the body) (alopecia) or hair growth (hypertrichosis)



Side effects which may occur with unknown frequency

- Allergic reactions, including rash, pruritus, urticaria, localised oedema, and angioedema
- Depression
- Pain and swelling in your 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, pharmacist or nurse. 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 this medicine.

5. How to store ACTASVO

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 30 °C.
- Store in the original container to protect from moisture.
- Do not use after the expiry date printed on the blister or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).



6. Contents of the pack and other information

What ACTASVO contains

The active substance is dutasteride. Each capsule contains 0,5 mg dutasteride.

The other ingredients are:

Content of the capsules: Butylhydroxytoluene (E-321), glycerol monocaprylocaprate.

Content of soft gelatine capsule: Gelatine, glycerol, lecithin (from soya) (E-322), titanium dioxide (E-171), triglycerides, yellow iron oxide (E-172).

What ACTASVO looks like and contents of the pack

ACTASVO is oblong, opaque and yellow soft gelatin capsules containing an oily and yellowish liquid.

ACTASVO soft capsules are packed in heat-sealed Aluminium/PVC-PVDC white opaque blister strips containing 10 capsules per blister. The blister strips are packed in outer cardboard cartons with a leaflet in a pack size of 30 capsules.

Holder of Certificate of Registration

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