SCHEDULING STATUS

S4

DUOZAQ 0,5 mg/0,4 mg capsules

Dutasteride and Tamsulosin hydrochloride

DUOZAQ 0,5 mg/0,4 mg is sugar-free

Read all of this leaflet carefully before you start taking DUOZAQ 0,5 mg/0,4 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DUOZAQ 0,5 mg/0,4 mg 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 DUOZAQ 0,5 mg/0,4 mg is and what it is used for

DUOZAQ 0,5 mg/0,4 mg 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.

DUOZAQ 0,5 mg/0,4 mg is used to treat men with an enlarged prostate (benign prostatic hyperplasia) - a noncancerous growth of the prostate gland.

2. What you need to know before you take DUOZAQ 0,5 mg/0,4 mg

Do not take DUOZAQ 0,5 mg/0,4 mg:

- if you are hypersensitive (allergic) to dutasteride, other 5-alpha reductase inhibitors, tamsulosin, or to any of the ingredients of DUOZAQ 0,5 mg/0,4 mg (see section 6)
- if you are female or under the age of 18 years as DUOZAQ 0,5 mg/0,4 mg is for use in adult men only
- if you have low blood pressure which makes you feel dizzy, lightheaded or faint (orthostatic hypotension)
- if you have severe liver disease.

Warnings and precautions

Take special care with DUOZAQ 0,5 mg/0,4 mg:

- women, children and adolescents must not handle leaking DUOZAQ 0,5 mg/0,4 mg 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.
- if you have liver disease, ask your doctor if DUOZAQ 0,5 mg/0,4 mg is suitable for you. Your doctor may want to perform regular medical check-ups whilst you are taking DUOZAQ 0,5 mg/0,4 mg.
- if you have heart failure (your heart does not pump blood as well as it should), inform your doctor about this, as your heart condition may worsen.
- DUOZAQ 0,5 mg/0,4 mg affects a blood test for PSA (prostate-specific antigen), which is sometimes used to detect prostate cancer. Men taking DUOZAQ 0,5 mg/0,4 mg should have their PSA measured 6 months after starting therapy and regularly thereafter. Although DUOZAQ 0,5 mg/0,4 mg will reduce the amount of PSA in your blood, you could still be at risk for prostate cancer. In spite of the effect DUOZAQ 0,5 mg/0,4 mg has on PSA count, your doctor can still use PSA level to detect prostate cancer by comparing your test result each time you have a PSA test.
- 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.
- DUOZAQ 0,5 mg/0,4 mg can lower your blood pressure, causing dizziness, light-headedness and fainting. Talk to your doctor should you experience any of these symptoms.

- if you are going to have cataract (cloudy lens) surgery, your doctor may ask you to stop taking DUOZAQ 0,5 mg/0,4 mg for a while before your operation.
- make sure your doctor knows if you have severe kidney disease.

Other medicines and DUOZAQ 0,5 mg/0,4 mg

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Do not take DUOZAQ 0,5 mg/0,4 mg with these medicines:

- other alpha-blockers e.g. doxazosin and prazosin (to treat high blood pressure), terazosin (to treat high blood pressure and benign prostatic hyperplasia), sildosin (to treat benign prostatic hyperplasia).

DUOZAQ 0,5 mg/0,4 mg is not recommended with these medicines:

- ketoconazole (to treat fungal infections) , paroxetine (used to treat depression), erythromycin (an antibiotic to treat infections).

Some medicines can react with DUOZAQ 0,5 mg/0,4 mg 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, as it can cause high blood pressure
- cimetidine (for stomach ulcers)
- warfarin (used in the treatment of blood clotting).

DUOZAQ 0,5 mg/0,4 mg with food and drink

DUOZAQ 0,5 mg/0,4 mg should be taken 30 minutes after the same meal everyday.

Pregnancy, breastfeeding and fertility

DUOZAQ 0,5 mg/0,4 mg is contraindicated for use in women.

Women who are pregnant (or may be) must not handle leaking capsules. Dutasteride, one of the active ingredients in DUOZAQ 0,5 mg/0,4 mg 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.

If you are a man using DUOZAQ 0,5 mg/0,4 mg, it is advised that you use condoms.

Driving and using machines

DUOZAQ 0,5 mg/0,4 mg makes some people feel dizzy, especially when standing up, so it may affect your ability to drive or operate machinery safely.

It is not always possible to predict to what extent DUOZAQ 0,5 mg/0,4 mg may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which DUOZAQ 0,5 mg/0,4 mg affects you.

3. How to take DUOZAQ 0,5 mg/0,4 mg

Do not share medicines prescribed for you with any other person. Always use DUOZAQ 0,5 mg/0,4 mg exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

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

The capsules should be swallowed whole and not chewed or opened.

Contact with the contents of the dutasteride yellow capsule (containing oily yellowish liquid) contained within the hard-shell capsule may make your mouth or throat sore.

Your doctor will tell you how long your treatment with DUOZAQ 0,5 mg/0,4 mg will last.

If you have the impression that the effect of DUOZAQ 0,5 mg/0,4 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more DUOZAQ 0,5 mg/0,4 mg than you should

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

If you forget to take DUOZAQ 0,5 mg/0,4 mg:

If you forget to take DUOZAQ 0,5 mg/0,4 mg, take as soon as you remember on the same day. If you do not take a tablet that same day, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking DUOZAQ 0,5 mg/0,4 mg

Don’t stop taking DUOZAQ 0,5 mg/0,4 mg without talking to your doctor first.

4. Possible side effects

DUOZAQ 0,5 mg/0,4 mg can have side effects.

Not all side effects reported for DUOZAQ 0,5 mg/0,4 mg are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while using DUOZAQ 0,5 mg/0,4 mg, please consult your healthcare provider for advice.

If any of the following happens, stop using DUOZAQ 0,5 mg/0,4 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, 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 DUOZAQ 0,5 mg/0,4 mg. You may need urgent medical attention or hospitalisation.

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

- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes, and genitals (Stevens-Johnson syndrome)
- irregular heartbeats and/or rapid heartbeats
- 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)

- your heart suddenly stops circulating blood throughout your body (cardiogenic shock).

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:

- dizziness
- 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)
- pain or swelling of the testicles.

Less frequent side effects:

- skin rash, hives, itching, swelling of hands and feet
- headache
- fast heartbeat (palpitations)
- fall in blood pressure on standing up which makes you feel dizzy or faint
- itchy, blocked, or runny nose (rhinitis)
- constipation, diarrhoea, vomiting, nausea
- persistent and painful erection of the penis (priapism)

- weakness or loss of strength.

The following side effects have been reported but the frequency for them to occur is not known:

- swelling in a specific area
- depressed mood
- hair loss (usually from the body) or hair growth, excessive sweating
- changes in vision (blurred vision or visual impairment), an eye condition called Floppy Iris Syndrome (a complication during cataract surgery)
- shortness of breath
- nosebleeds
- liver problems (if you experience a sudden onset of nausea, weakness, fatigue, abdominal pain and sleepiness contact your doctor to do blood tests).

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. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reporting Form”, found on SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8.

An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

By reporting side effects, you can help provide more information on the safety of DUOZAQ 0,5 mg/0,4 mg.

5. How to store DUOZAQ 0,5 mg/0,4 mg

Store all medicines out of reach of children.

Store at or below 30 ºC.

Keep blisters in carton until required for use.

Keep bottle closed until required for use.

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 DUOZAQ 0,5 mg/0,4 mg contains

The hard capsules contain: one dutasteride 0,5 mg soft gelatin capsule (yellow) and tamsulosin HCl pellets (white to off-white) in the equivalent weight of 0,4 mg of tamsulosin HCl.

The other ingredients are:

Dutasteride soft capsules

Butylhydroxytoluene (BHT), gelatin, glycerol, glycerol monocaprylocaprate, lecithin (soya), titanium dioxide, triglycerides - medium chain, yellow iron oxide.

Tamsulosin pellets

Magnesium stearate, ethacrylic acid –ethyl acrylate copolymer (1:1), methacrylic acid –ethyl acrylate copolymer (1:1), dispersion (30%), microcrystalline cellulose, purified talc, sodium hydroxide, titanium dioxide, triacetin, talc.

Hard capsules

Carrageenan, hypromellose, potassium chloride, red iron oxide, sunset yellow, titanium dioxide.

What DUOZAQ 0,5 mg/0,4 mg looks like and contents of the pack

DUOZAQ 0,5 mg/0,4 mg is a hard capsule with brown body and orange cap.

30 capsules: Alu-Alu blisters are packed in a printed outer carton (30 capsules).

HDPE bottles containing 30 capsules are packed in a printed outer carton.

* Not all pack presentations may be marketed.

Holder of Certificate of Registration

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