

Avozaq SR 0,4 mg
Pharma Dynamics (Pty) Ltd

Each hard gelatin capsule contains 0,40 mg
tamsulosin hydrochloride.

Clinical Approved: 07 February 2025

Registration Approval: 03 June 2025

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

AVOZAQ SR 0,4 mg hard gelatin capsules

Tamsulosin hydrochloride

AVOZAQ SR 0,4 mg is sugar-free

Read all of this leaflet carefully before you start taking AVOZAQ 0,4 mg SR

- 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.
- AVOZAQ SR 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 AVOZAQ SR 0,4 mg is and what it is used for
2. What you need to know before you use AVOZAQ 0,4 mg SR
3. How to take AVOZAQ 0,4 mg SR
4. Possible side effects
5. How to store AVOZAQ 0,4 mg SR
6. Contents of the pack and other information

Avozaq SR 0,4 mg
Pharma Dynamics (Pty) Ltd

Each hard gelatin capsule contains 0,40 mg
tamsulosin hydrochloride.

Clinical Approved: 07 February 2025

Registration Approval: 03 June 2025

APPROVED PATIENT INFORMATION LEAFLET

1. What AVOZAQ SR 0,4 mg is and what it is used for

AVOZAQ SR 0,4 mg contains the active substance tamsulosin, which reduces the tension in muscles of the prostate and urethra. Easier urination occurs due to easier flow of urine through the urethra.

AVOZAQ SR 0,4 mg is used in men for the treatment of difficulties associated with benign enlargement of the prostate such as: difficult urination, urinary dribbling, strong urge to urinate, frequent urination during the night as well as during the day.

2. What you need to know before you take AVOZAQ 0,4 mg SR

Do not take AVOZAQ 0,4 mg SR:

- if you are hypersensitive (allergic) to tamsulosin hydrochloride, or to any of the ingredients of AVOZAQ SR 0,4 mg (see section 6)
- if you suffer from dizziness when you want to sit up or stand up from the lying position (orthostatic hypotension)
- if you suffer from a serious infection of the liver
- if you are on medicines which block the function of an important enzyme (CYP3A4), such as ketoconazole, used to treat fungal infections

Avozaq SR 0,4 mg
Pharma Dynamics (Pty) Ltd

Each hard gelatin capsule contains 0,40 mg
tamsulosin hydrochloride.

Clinical Approved: 07 February 2025

Registration Approval: 03 June 2025

APPROVED PATIENT INFORMATION LEAFLET

Warnings and precautions

Take special care with AVOZAQ 0,4 mg SR:

On long-term use of this medicine, regular medical examinations are necessary.

- infrequently, drop in blood pressure (orthostatic hypotension) has been reported during the use of the AVOZAQ 0,4 mg SR. On first feeling of dizziness/weakness, the patient should sit down or lie down until these symptoms have disappeared.
- your doctor or healthcare provider will conduct an examination, prior to prescribing AVOZAQ SR 0,4 mg in order to rule out any conditions you may have that could cause the same symptoms as benign enlargement of the prostate
- your doctor or healthcare provider will conduct a digital rectal examination, and when necessary, determination of prostate specific antigen (PSA) before treatment and at regular intervals afterwards
- if you have severely impaired kidney function your doctor or healthcare provider will monitor your progress closely
- if you are planning to undergo cataract (cloudy lens) or glaucoma (increased pressure in the eye) surgery, please inform your doctor that you are taking or have recently taken AVOZAQ 0,4 mg SR.

The specialist can then take appropriate precautions with respect to medication and surgical techniques to be used. Ask your doctor whether or not you should postpone or temporarily stop taking this medicine when undergoing eye surgery because of cataracts or glaucoma

Avozaq SR 0,4 mg
Pharma Dynamics (Pty) Ltd

Each hard gelatin capsule contains 0,40 mg
tamsulosin hydrochloride.

Clinical Approved: 07 February 2025

Registration Approval: 03 June 2025

APPROVED PATIENT INFORMATION LEAFLET

- AVOZAQ SR 0,4 mg capsules can cause a painful erection (priapism), which cannot be relieved by having sex. If this happens, get medical help right away. If priapism is not treated, you may not be able to get an erection in the future.

Other medicines and AVOZAQ 0,4 mg SR

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

Other medicines may be affected by AVOZAQ 0,4 mg SR. They, in turn, may affect how well AVOZAQ SR 0,4 mg works. AVOZAQ SR 0,4 mg may interact with:

- cimetidine (used to treat ulcers; gastroesophageal reflux disease) may increase the effect of AVOZAQ 0,4 mg SR
- furosemide (water tablets) may lower the effect of AVOZAQ 0,4 mg SR
- diclofenac (a pain killer and anti-inflammatory medicine) can speed up the removal of AVOZAQ SR 0,4 mg from your body, thereby shortening the time AVOZAQ SR 0,4 mg is effective
- warfarin (used to prevent blood clotting) can speed up the removal AVOZAQ SR 0,4 mg from your body, thereby shortening the time AVOZAQ SR 0,4 mg is effective
- ketoconazole (used to treat fungal infections) may increase the effects of AVOZAQ SR 0,4 mg (see Do not take AVOZAQ 0,4 mg SR)
- erythromycin (an antibiotic for infection) may also increase the effects of AVOZAQ SR 0,4 mg
- paroxetine (anti-depressant) may increase the effect of AVOZAQ 0,4 mg SR
- another alpha-adrenoceptor blocker (used to treat high blood pressure), e.g.,

Avozaq SR 0,4 mg
Pharma Dynamics (Pty) Ltd

Each hard gelatin capsule contains 0,40 mg
tamsulosin hydrochloride.

Clinical Approved: 07 February 2025

Registration Approval: 03 June 2025

APPROVED PATIENT INFORMATION LEAFLET

doxazosin and terazosin, when taken with AVOZAQ SR 0,4 mg may lower your blood pressure, causing dizziness or light-headedness

- taking AVOZAQ SR 0,4 mg with PDE5 inhibitors (medicine used to treat erectile dysfunction), e.g., sildenafil, tadalafil, may cause low blood pressure

Pregnancy, breastfeeding, and fertility

AVOZAQ SR 0,4 mg is not for use in women.

Fertility

Difficulties with ejaculation have been reported in association with AVOZAQ SR 0,4 mg use (see section 4). Ejaculation disorders may occur.

Driving and using machines

You may experience dizziness which may affect your ability to drive or operate machinery.

It is not always possible to predict to what extent AVOZAQ SR 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 AVOZAQ SR 0,4 mg affects you.

3. How to take AVOZAQ 0,4 mg SR

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

Avozaq SR 0,4 mg
Pharma Dynamics (Pty) Ltd

Each hard gelatin capsule contains 0,40 mg
tamsulosin hydrochloride.

Clinical Approved: 07 February 2025

Registration Approval: 03 June 2025

APPROVED PATIENT INFORMATION LEAFLET

Adults

The usual dose is one capsule daily, taken after breakfast, or after the first daily meal.

Children

AVOZAQ SR 0,4 mg is not for use in children under the age of 18.

Your doctor will tell you how long your treatment with AVOZAQ SR 0,4 mg will last.

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

If you take more AVOZAQ SR 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.

Symptoms of overdose may include:

- Drop in blood pressure can occur after overdosage. You may experience the following symptoms – confusion, dizziness or headaches, shortness of breath, irregular heartbeats, or fever.

If you forget to take AVOZAQ 0,4 mg SR:

If you forget to take AVOZAQ 0,4 mg SR, take the medicine 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.

Avozaq SR 0,4 mg
Pharma Dynamics (Pty) Ltd

Each hard gelatin capsule contains 0,40 mg
tamsulosin hydrochloride.

Clinical Approved: 07 February 2025

Registration Approval: 03 June 2025

APPROVED PATIENT INFORMATION LEAFLET

If you stop taking AVOZAQ 0,4 mg SR

Do not stop taking without medical advice from your doctor.

4. Possible side effects

AVOZAQ SR 0,4 mg can have side effects.

Not all side effects reported for AVOZAQ SR 0,4 mg are included in this leaflet.

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

If any of the following happens, stop using AVOZAQ SR 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 AVOZAQ 0,4 mg SR. You may need urgent medical attention or hospitalisation.

Avozaq SR 0,4 mg
Pharma Dynamics (Pty) Ltd

Each hard gelatin capsule contains 0,40 mg
tamsulosin hydrochloride.

Clinical Approved: 07 February 2025

Registration Approval: 03 June 2025

APPROVED PATIENT INFORMATION LEAFLET

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

- increased or fast heartbeat (tachycardia), irregular or rapid heartbeat or slow heartbeat (palpitations/dysrhythmia) abnormally fast heartbeat (atrial fibrillation)
- rashes, blister, peeling rash of small purplish spots, red spots, or small bump on any part of your skin with or without a rash (including your lips, eyes, mouth, nose, genitals, hands or feet), flu-like symptoms (fever, chills or aching muscles) which are symptoms of a serious skin reaction (Steven Johnson Syndrome) which could be fatal
- skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet.

These could be signs of a serious skin allergy called 'erythema multiforme.

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
- sleepiness (somnolence)
- difficulty in sleeping (insomnia)
- ejaculation disorders, retrograde ejaculation (dry ejaculation - when semen enters the bladder instead of emerging through the penis during orgasm), ejaculation failure.

Avozaq SR 0,4 mg
Pharma Dynamics (Pty) Ltd

Each hard gelatin capsule contains 0,40 mg
tamsulosin hydrochloride.

Clinical Approved: 07 February 2025

Registration Approval: 03 June 2025

APPROVED PATIENT INFORMATION LEAFLET

Less frequent side effects:

- headache
- light-headedness as you sit or stand up (orthostatic hypotension) or fainting (syncope)
- swelling and irritation inside the nose (rhinitis), inflammation of the throat (pharyngitis), cough increased, sinusitis
- constipation, diarrhoea, nausea, vomiting, tooth disorder
- skin irritation/itch that needs to be scratched, hives
- painful long-lasting unwanted erection which requires immediate medical assistance (priapism)
- feeling of weakness or lack of energy (asthenia)
- infection, back pain, chest pain

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

- blurred vision, vision disturbances, weak pupillary dilation and a stretchy iris (intraoperative floppy iris syndrome, IFIS)
- nose bleeds (epistaxis), difficulty breathing (dyspnoea)
- dry mouth
- superficial reddening of the skin, usually in patches, and scaling of the skin (exfoliative dermatitis), skin peeling.

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

Avozaq SR 0,4 mg
Pharma Dynamics (Pty) Ltd

Each hard gelatin capsule contains 0,40 mg
tamsulosin hydrochloride.

Clinical Approved: 07 February 2025

Registration Approval: 03 June 2025

APPROVED PATIENT INFORMATION LEAFLET

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of AVOZAQ 0,4 mg SR. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store AVOZAQ 0,4 mg SR

Store all medicines out of reach of children.

Store at or below 25 °C in a cool, dry place.

Keep blisters in carton until required for use.

Do not use after the expiry date stated on the carton and/or blister. 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 AVOZAQ SR 0,4 mg contains

Each capsule contains 0,40 mg tamsulosin hydrochloride.

Avozaq SR 0,4 mg
Pharma Dynamics (Pty) Ltd

Each hard gelatin capsule contains 0,40 mg
tamsulosin hydrochloride.

Clinical Approved: 07 February 2025

Registration Approval: 03 June 2025

APPROVED PATIENT INFORMATION LEAFLET

The other ingredients are:

Calcium stearate, colloidal hydrous silica, dibutyl sebacate, microcrystalline cellulose, metacrylic acid – ethyl acrylate copolymer dispersion (methacrylic acid, ethyl acrylate copolymer, sodium lauryl sulfate, polysorbate), polysorbate 80.

Capsules

Black iron oxide, gelatin, indogotone – FD&C Blue 2, titanium dioxide, red iron oxide, yellow iron oxide.

What AVOZAQ SR 0,4 mg looks like and contents of the pack

AVOZAQ SR 0,4 mg capsules are sustained-release hard gelatin capsules, with an orange body and olive cap containing white to off white pellets.

AVOZAQ SR 0,4 mg capsules are packed into PVC/PVDC – Aluminium blisters consisting of 10 or 15 capsules per blisters. These blisters are packed into an outer carton with a leaflet.
Pack sizes: 10, 20, 30, 50, 90, 100 capsules*.

* Not all pack sizes will be marketed.

Avozaq SR 0,4 mg
Each capsule contains 0,4 mg Tamsulosin HCl

Pharma Dynamics (Pty) Ltd
fcdijeiajahjda

Avozaq SR 0,4 mg
Pharma Dynamics (Pty) Ltd

Each hard gelatin capsule contains 0,40 mg
tamsulosin hydrochloride.

Clinical Approved: 07 February 2025

Registration Approval: 03 June 2025

APPROVED PATIENT INFORMATION LEAFLET

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

or 0860-PHARMA (742 762)

This leaflet was last revised in

03 June 2025

REGISTRATION NUMBER

57/34/0289