

Austell Pharmaceuticals (Pty) Ltd, 540107 and 540108, SILDOS 4 mg and SILDOS 8 mg, Hard gelatin capsules, 4 mg and 8 mg.

Approved Patient Information Leaflet for Medicines for Human Use:

SILDOS

SCHEDULING STATUS: S4

SILDOS 4 mg and SILDOS 8 mg

silodosin

hard gelatin capsules

Contains sugar:

SILDOS 4 mg: Each hard gelatin capsule contains 117 mg/capsule mannitol.

SILDOS 8 mg: Each hard gelatin capsule contains 234 mg/capsule mannitol.

Read all of this leaflet carefully before you start taking SILDOS.

- 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.
- SILDOS 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 SILDOS is and what it is used for
2. What you need to know before you take SILDOS
3. How to take SILDOS
4. Possible side effects
5. How to store SILDOS

6. Contents of the pack and other information

1. What SILDOS is and what it is used for

SILDOS belongs to a group of medicines called α_{1A} -adrenoreceptor blockers. SILDOS is selective for the receptors located in the prostate, bladder and urethra. By blocking these receptors, it causes smooth muscle in these tissues to relax. This makes it easier for you to pass water and relieves your symptoms.

SILDOS is used in adult men to treat the urinary symptoms associated with benign enlargement of the prostate (prostatic hyperplasia), such as:

- difficulty in starting to pass water,
- a feeling of not completely emptying the bladder,
- a more frequent need to pass water, even at night

2. What you need to know before you take SILDOS

SILDOS should not be administered to you

- if you are hypersensitive (allergic) to silodosin or any of the other ingredients of SILDOS (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking SILDOS

- If you are undergoing eye surgery because of cloudiness of the lens (**cataract surgery**), it is important that *you immediately inform your eye specialist* that you are using or have previously used SILDOS. This is because some patients treated with this kind of medicine experienced a loss of muscle tone in the iris (the

coloured circular part of the eye) during such a surgery. The specialist can take appropriate precautions with respect to medicine and surgical techniques to be used. Ask your doctor whether or not you should postpone or temporarily stop taking SILDOS when undergoing cataract surgery.

- If you have ever fainted or felt dizzy when suddenly standing up, please inform your doctor before taking SILDOS. **Dizziness** when standing up and occasionally **fainting** may occur when taking SILDOS, particularly when starting treatment or if you are taking other medicines that lower blood pressure. If this occurs, make sure you *sit or lie down* straight away until the symptoms have disappeared and *inform your doctor as soon as possible* (see also section “Driving and using machines”).
- If you have **severe liver problems**, you should not take SILDOS as it was not tested in this condition.
- If you have **problems with your kidneys**, please ask your doctor for advice. If you have moderate kidney problems, your doctor will start SILDOS with caution and possibly with a lower dose (see section “How to take Sildos”). If you have severe kidney problems, you should not take SILDOS.
- Since a benign enlargement of the prostate and prostate cancer may present the same symptoms, your doctor will check you for prostate cancer before starting treatment with SILDOS. SILDOS does not treat prostate cancer.
- The treatment with SILDOS may lead to an abnormal ejaculation (decrease in the amount of semen released during sex) that may temporarily affect male fertility. This effect disappears after

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discontinuation of SILDOS. Please inform your doctor if you are planning to have children.

Children and adolescents

Do not give this medicine to children and adolescents below 18 years since there is no relevant indication for this age group.

Other medicines and SILDOS

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

Tell your doctor in particular, if you take:

- **medicines which lower blood pressure** (in particular, medicines called α_1 -blockers, such as prazosin or doxazosin) as there may be the potential risk that the effect of these medicines is increased whilst taking SILDOS.
- **antifungal medicines** (such as ketoconazole or itraconazole), **medicines used for HIV-AIDS** (such as ritonavir) or **medicines used after transplants to prevent organ rejection** (such as ciclosporin) because these medicines can increase the blood concentration of SILDOS.
- **medicines used for treating problems in getting or keeping an erection** (such as sildenafil or tadalafil), since the concomitant use with SILDOS might lead to a slight decrease in blood pressure.
- **medicines for epilepsy or rifampicin** (a medicine to treat tuberculosis) since the effect of SILDOS may be reduced.

Pregnancy, breastfeeding and fertility

Not applicable as silodosin is intended for male patients only.

Driving and using machines

Do not drive or operate machines if you feel faint, dizzy, drowsy or have blurred vision. It is not always possible to predict to what extent SILDOS 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 SILDOS affects you.

3. How to take SILDOS

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

Always take SILDOS exactly as your health care provider has told you.

Check with your health care provider if you are not sure.

The recommended dose is one capsule of SILDOS 8 mg per day by oral administration. Always take the capsule with food, preferably at the same time every day. Do not break or chew the capsule, but swallow it whole, preferably with a glass of water.

Your doctor will tell you how long your treatment with SILDOS will last.

Patients with kidney problems

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If you have moderate kidney problems, your doctor may prescribe a different dose. For this purpose, SILDOS 4 mg hard capsules are available.

If you take more SILDOS than you should

If you have taken more than one capsule, inform your doctor as soon as possible. If you become dizzy or feel weak, tell your doctor straight away.

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 SILDOS

You may take your capsule later the same day if you have forgotten to take it earlier. If it is almost time for the next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten capsule.

If you stop taking SILDOS

If you stop treatment, your symptoms may re-appear.

If you have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

SILDOS can have side effects.

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

If any of the following happens, stop taking SILDOS and tell your health care provider immediately or go to the casualty department at your nearest hospital: swelling of the face or throat, difficulty in breathing, feeling faint, itchy skin or hives.

These are very serious side effects. If you have them, you may have had a serious reaction to SILDOS. 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:

- Any changes in your vision following cataract surgery, SILDOS may cause complications during cataract surgery.
- Dizziness, weakness or fainting.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Abnormal ejaculation (less or no noticeable semen is released during sex, see section “Warnings and precautions”)
- Dizziness, including dizziness when standing up
- Runny or blocked nose
- Diarrhoea

Less frequent side effects:

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- Decreased sexual drive
- Nausea
- Dry mouth
- Difficulties in getting or keeping an erection
- Abnormal results of liver function tests
- Low blood pressure
- Fast or irregular heart beats (called palpitations)
- Fainting/ Loss of consciousness

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 health care provider. You can also report side effects to SAHPRA via the "Adverse drug reaction and quality problem reporting form", found online under SAHPRA's publications: <https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/>. By reporting side effects, you can help provide more information on the safety of SILDOS.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store SILDOS

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package in order to protect from light.

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Return all unused medicine to your pharmacist.

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

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What SILDOS contains

- The active substance is silodosin
- The other ingredients are gelatin, glycerol, iron, mannitol, printing ink – black, sodium, starch, pregelatinised (maize) titanium dioxide, water purified

What SILDOS looks like and contents of the pack

SILDOS 4 mg: Yellow, opaque, hard gelatin capsule, size 3, printed with black ink “4” on the cap.

SILDOS 8 mg: White, opaque, hard gelatin capsule, size 0, printed with black ink “8” on the cap.

SILDOS is supplied in PVC/PVDC/aluminum foil blisters, packed in cartons. Packs of 5, 10, 20, 30, 50, 90, 100 capsules

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Registration Application numbers

SILDOS 4 mg: 54/32.2/0107

SILDOS 8 mg: 54/32.2/0108

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following

URL: <https://austell.co.za/product-info/>

Austell Pharmaceuticals (Pty) Ltd

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