PROPOSED CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

SILODYX 4 mg hard gelatin capsules

SILODYX 8 mg hard gelatin capsules

Silodosin

Contains sugar: mannitol

SILODYX 4 mg contains 132,4 mg mannitol per capsule.

SILODYX 4 mg contains 264,8 mg mannitol per capsule.

Read all of this leaflet carefully before you start taking SILODYX

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

1. What SILODYX is and what it is used for

SILODYX belongs to a group of medicines called alpha$_{1A}$-adrenoreceptor blockers. **SILODYX** 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.

SILODYX is used in adult male patients 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, or
- a more frequent need to pass water, even at night.

2. What you need to know before you take SILODYX

Do not take SILODYX:

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

Warnings and precautions

Take special care with SILODYX:

- 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 **SILODYX**. 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 **SILODYX** when undergoing cataract surgery.
- If you have ever fainted or felt dizzy when suddenly standing up, please inform your doctor before taking **SILODYX**. **Dizziness** when standing up and occasionally **fainting** may occur when taking **SILODYX**, 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 machinery**).
- If you have **severe liver problems**, you should not take **SILODYX**, 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 **SILODYX** with caution and possibly with a lower dose (see **How to take SILODYX**). If you have severe kidney problems, you should not

take **SILODYX**.

- 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 **SILODYX**. **SILODYX** does not treat prostate cancer.
- The treatment with **SILODYX** 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 discontinuation of **SILODYX**. Please inform you doctor if you are planning to have children.
- Do not give **SILODYX** to children and adolescents below 18 years since there is no relevant indication for this age group.

Other medicines and SILODYX

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 alpha$_1$-blockers, such as prazosin or doxazosin), as there may be the potential risk that the effect of these medicines ~~may be~~ is increased whilst taking silodosin.
- **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 cyclosporin) because these medicines can increase the blood concentration of **SILODYX**.
- **medicines used for treating problems in getting or keeping an erection** (such as sildenafil or tadalafil), since the concomitant use with SILODYX might lead to a slight decrease in blood pressure.
- **medicines for epilepsy** (such as barbiturates, carbamazepine, phenytoin) **or rifampicin** (a medicine to treat tuberculosis), since the effect of **SILODYX** may be reduced.

SILODYX with food or drink

Always take **SILODYX** with food (see **When and how to take SILODYX**).

Pregnancy and breastfeeding

SILODYX is intended for male patients only. Please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machines

Do not drive or operate machines if you feel faint, dizzy, drowsy or have blurred vision.

SILODYX contains mannitol

SILODYX capsules contain mannitol and may have a laxative effect.

3. How to take SILODYX

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

Always take **SILODYX** exactly as your doctor has told you. You should check with your doctor if you are unsure.

If you have the impression that the effect of **SILODYX** is too strong or too weak, talk to your doctor or pharmacist.

Dose:

The **usual dose** is one capsule of **SILODYX 8 mg** per day by oral administration.

Patients with kidney problems

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

When and how to take SILODYX

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.

If you take more SILODYX than you should

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 control centre.

If you forget to take SILODYX

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 forgotten individual doses.

Effects when treatment with SILODYX is stopped

If you stop treatment, your symptoms may reappear.

4. Possible side effects

SILODYX can have side effects.

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

If any of the following happens, stop taking **SILODYX** 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 reaction to **SILODYX**. You may need urgent medical attention or hospitalisation.

The most common side effect is a decrease in the amount of semen released during sex. This effect disappears after discontinuation of **SILODYX**. Please inform your doctor if you are planning to have children.

Dizziness, including dizziness when standing up, and occasionally fainting, may occur. If you do feel weak or dizzy, make sure you sit or lie down straight away until the symptoms have disappeared. If dizziness when standing up or fainting occurs, please inform your doctor as soon as possible.

SILODYX may cause complications during a cataract surgery (eye surgery because of cloudiness of the lens).

It is important that you immediately inform your eye specialist if you are using or have previously used **SILODYX**.

The possible side effects are listed below:

Very common side effects (may affect more than 1 in 10 people)

- Abnormal ejaculation (less or no noticeable semen is released during sex)

Common side effects (may affect up to 1 in 10 people)

- Dizziness, including dizziness when standing up
- Runny or blocked nose
- Diarrhoea

Uncommon side effects (may affect up to 1 in 100 people)

- Decreased sexual drive
- Nausea
- Dry mouth
- Difficulties in getting or keeping an erection
- Faster heart rate
- Symptoms of allergic reaction affecting the skin like rash, itching, hives and rash caused by a medicine
- Abnormal results of liver function tests
- Low blood pressure

Rare side effects (may affect up to 1 in 1,000 people)

- Fast or irregular heart beats (called palpitations)
- Fainting/ Loss of consciousness

Very rare side effects (may affect up to 1 in 10,000 people)

- Other allergic reactions with swelling of the face or throat

Not known (frequency cannot be estimated from the available data)

- Floppy pupil during cataract surgery

If you feel that your sexual life is affected, please tell your doctor.

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. You can also report side effects to SAHPRA via the Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions 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 **SILODYX**.

5. How to store SILODYX

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Store in the original package in order to protect from light and moisture. Do not remove blisters from carton until required for use.

- Do not use **SILODYX** after the expiry date which is stated on the carton and blister after the abbreviation EXP. The expiry date refers to the last day of that month.
- Do not use any **SILODYX** pack that is damaged or shows signs of tampering.

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 SILODYX contains

SILODYX 4 mg

The active substance is silodosin. Each capsule contains 4 mg of silodosin.

The other ingredients are gelatine, magnesium stearate, mannitol (E421), pregelatinised maize starch, sodium lauryl sulphate, titanium dioxide (E171), yellow iron oxide (E172).

SILODYX 8 mg

The active substance is silodosin. Each capsule contains 8 mg of silodosin.

The other ingredients are gelatine, magnesium stearate, mannitol (E421), pregelatinised maize starch, sodium lauryl sulphate, titanium dioxide (E171).

What SILODYX looks like and contents of the pack

SILODYX 4 mg are opaque yellow size 3 hard gelatine capsules containing white to pale yellowish fine particles and/or powder.

SILODYX 8 mg are opaque white size 0 hard gelatine capsules containing white to pale yellowish fine particles and/or powder.

SILODYX is available in opaque white PVC-PVDC/Aluminium blister packs.

Pack sizes available:

5 capsules (one blister per carton)

10 capsules (one blister per carton)

20 capsules (two blisters per carton)

30 capsules (three blisters per carton)

50 capsules (five blisters per carton)

90 capsules (nine blisters per carton)

100 capsules (ten blisters per carton).

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd

106 16th Road

MIDRAND

This leaflet was last revised in

15 September 2022

Registration numbers

SILODYX 4 mg: 45/32.2/0118

SILODYX 8 mg: 45/32.2/0119

Access to the corresponding Professional Information

To be confirmed.

SILODYX 4 mg

NAMIBIA:
Scheduling status: NS2
Registration no.:

SILODYX 8 mg

NAMIBIA:
Scheduling status: NS2
Registration no.: