PACKAGE LEAFLET

Package leaflet: Information for the patient

Silodosine Sandoz 4 mg, harde capsules
Silodosine Sandoz 8 mg, harde capsules

silodosin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What {[nationally completed name]} is and what it is used for

What {[nationally completed name]} is

{[Nationally completed name]} belongs to a group of medicines called alpha$_{1A}$-adrenoreceptor blockers. {[Nationally completed name]} 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.

What {[nationally completed name]} is used for

{[Nationally completed name]} 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 {[nationally completed name]}

Do not take {[nationally completed name]}

If you are allergic to silodosin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before taking {[nationally completed name]}

- 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 {[nationally completed name]}. 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 {[nationally completed name]} when undergoing cataract surgery.

- If you have ever fainted or felt dizzy when suddenly standing up, please inform your doctor before taking {[nationally completed name]}.
  Dizziness when standing up and occasionally fainting may occur when taking {[nationally completed name]}, 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 {[nationally completed name]}, 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 {[nationally completed name]} with caution and possibly with a lower dose (see Section 3).
  If you have severe kidney problems, you should not take {[nationally completed name]}.

- 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 {[nationally completed name]}. {[Nationally completed name]} does not treat prostate cancer.

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 {[nationally completed name]}

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor in particular, if you take:
- **medicines which lower blood pressure** (in particular, medicines called alpha1-blockers, such as prazosin or doxazosin) as there may be the potential risk that the effect of these medicines is increased whilst taking {[nationally completed name]}.
- **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 {[nationally completed name]}.
- **medicines used for treating problems in getting or keeping an erection** (such as sildenafil or tadalafil), since the concomitant use with {[nationally completed name]} might lead to a slight decrease in blood pressure.
- **medicines for epilepsy or rifampicin** (a medicine to treat tubercolosis), since the effect of {[nationally completed name]} may be reduced.

Fertility

The treatment with {[nationally completed name]} 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 {[nationally completed name]}. Please inform your doctor if you are planning to have children.

Driving and using machines

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

{[Nationally completed name]} contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium-free’.

3. How to take {[nationally completed name]}

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one capsule of {[nationally completed name]} 8 mg per day by oral administration.

Take the capsule always 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.

<u>Patients with kidney problems</u>
If you have moderate kidney problems, your doctor may prescribe a different dose.
For this purpose {[nationally completed name]} 4 mg hard capsules are available.

If you take more {[nationally completed name]} 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.

If you forget to take {[nationally completed name]}

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 {[nationally completed name]}

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor immediately if you notice any of the following allergic reactions: swelling of the face or throat, difficulty in breathing, feeling faint, itchy skin or hives since the consequences could become serious.

The most common side effect is a decrease in the amount of semen released during sex. This effect disappears after discontinuation of {[nationally completed name]}. 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.

{[Nationally completed name]} may cause complications during a **cataract surgery** (eye surgery because of cloudiness of the lens, see section “Warnings and precautions”).
It is important that you immediately inform your eye specialist if you are using or have previously used {[nationally completed name]}.

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, see Section “Fertility”)

Common side effects (may affect up to 1 in 10 people)
- Dizziness, including dizziness when standing up (see also above, in this section)
- 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 heartbeats (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 (see also above, in this section)

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

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store {[nationally completed name]}

Keep this medicine out of the sight and reach of children.

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

Store in the original package in order to protect from light. Do not store above 30°C

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What {[nationally completed name]} contains

<{[Nationally completed name] 4 mg capsule, hard}>
- The active substance is silodosin. Each hard capsule contains 4 mg silodosin.

<{[Nationally completed name] 8 mg capsule, hard}>
- The active substance is silodosin. Each hard capsule contains 8 mg silodosin.

- The other ingredients are
Capsule content: mannitol (E421), pregelatinised starch, sodium laurylsulfate (E487), magnesium stearate (E470b)
Capsule shell: titatium dioxide (E171), gelatin (E441)
Printing ink: shellac (E904), black iron oxide (E172), potassium hydroxide (E525)

What {[nationally completed name]} looks like and contents of the pack

<{[Nationally completed name] 4 mg capsule, hard}>
White hard capsule inked with an “S” in the lid and a “4” in the body, containing a white or almost white fine powder.
Length approx. 29.2 mm

<{[Nationally completed name] 8 mg capsule, hard}>
White hard capsule inked with an “S” in the lid and an “8” in the body, containing white or almost white fine powder.
Length approx. 21.7 mm

{[Nationally completed name]} are packed in PVC/PVDC-aluminium blisters.

Pack size
<Blister pack: 30 hard capsules.>
<Unit dose blister pack: 10x1 and 30x1 hard capsules.>

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
Sandoz B.V.
Veluwezoom 22
1327 AH Almere
Nederland

Fabrikant
Noucor Health, S.A.Av. Cami Reial, 51-57

08184 – Palau-solità i Plegamans
Barcelona, Spanje

Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

Dit geneesmiddel staat in het register ingeschreven onder:

Silodosine Sandoz 4 mg, harde capsules	RVG 122984
Silodosine Sandoz 8 mg, harde capsules	RVG 122985

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Spanje	Silodosina Sandoz 4 mg cápsulas duras EFG
	Silodosina Sandoz 8 mg cápsulas duras EFG
Frankrijk	SILODOSINE SANDOZ 4 mg, gélule
	SILODOSINE SANDOZ 8 mg, gélule
Italië	Silodosina Sandoz
Portugal	Silodosina Sandoz
Slovenië	Silodozin Sandoz 4 mg trde kapsule
	Silodozin Sandoz 8 mg trde kapsule
Nederland	Silodosine Sandoz 4 mg, harde capsule
	Silodosine Sandoz 4 mg, harde capsule

Deze bijsluiter is voor het laatst goedgekeurd in augustus 2022.