

SILOSIN[®]

4 mg and 8 mg hard capsules
Silodosin

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Silosin is and what it is used for
2. Before you take Silosin
3. How to take Silosin
4. Possible side effects
5. How to store Silosin
6. Further information

1. WHAT SILOSIN IS AND WHAT IT IS USED FOR

What Silosin is

Silosin belongs to a group of medicines called α_{1A} -adrenoreceptor blockers. Silosin 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 Silosin is used for

Silosin is used in 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
- a more frequent need to pass water, even at night.

2. BEFORE YOU TAKE SILOSIN

Do NOT take Silosin

- You must not take Silosin if you are allergic (hypersensitive) to silodosin or any of the other ingredients of this medicine.

Take special care with Silosin

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 Silosin. 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 Silosin when undergoing cataract surgery.

If you have ever fainted or felt dizzy when suddenly standing up, please inform your doctor before taking Silosin. Dizziness when standing up and occasionally fainting may occur when taking Silosin, 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 section "Driving and using machines").

- If you have severe liver problems, you should not take Silosin, 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 Silosin with caution and possibly with a lower dose (see section "How to take Silosin").

If you have severe kidney problems, you should not take Silosin.

- 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 Silosin. Silosin does not treat prostate cancer.

- The treatment with Silosin 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 Silosin. Please inform your doctor if you are planning to have children.
- Silosin is not recommended for use in patients aged below 18 years since there is no relevant indication for this age group.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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 Silosin.
- 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 Silosin.
- medicines used for treating problems in getting or keeping an erection (such as sildenafil or tadalafil), since the concomitant use with Silosin might lead to a slight decrease in blood pressure.
- medicines for epilepsy or rifampicin (a medicine to treat tuberculosis), since the effect of Silosin may be reduced.

Taking Silosin with food and drink

Take Silosin always with food (see section "When and how to take Silosin").

Pregnancy and lactation

Not applicable as Silosin 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.

3. HOW TO TAKE SILOSIN

Always use Silosin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage

The recommended dose is one capsule of Silosin 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 Silosin 4 mg hard capsules are available.

When and how to take Silosin

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.

If you use more Silosin 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 use Silosin

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 using Silosin

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Silosin 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, diffi-

culty 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 Silosin. 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.

Silosin may cause a complication called Intraoperative Floppy Iris Syndrome (IFIS) during a cataract surgery (eye surgery because of cloudiness of the lens, see section "Take special care with Silosin").

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

The frequency of possible side effects listed below is defined using the following convention:

Very common: $\geq 1/10$

Common: $\geq 1/100$ to $< 1/10$

Uncommon: $\geq 1/1,000$ to $< 1/100$

Rare: $\geq 1/10,000$ to $< 1/1,000$

Very rare: $< 1/10,000$

Not known: frequency cannot be estimated from available data.

• Very common side effects: Abnormal ejaculation (less or no noticeable semen is released during sex, see section "Take special care with Silosin").

• Common side effects: Dizziness, including dizziness when standing up (see also above, in this section); Runny or blocked nose; Diarrhea

• Uncommon side effects: 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: Fast or irregular heart beats (called palpitations); Fainting/ loss of consciousness

• Very rare side effects: Other allergic reactions with swelling of the face or throat

• Not known side effects: Floppy pupil during cataract surgery (see also above, in this section).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

5. HOW TO STORE SILOSIN

Keep out of the reach and sight of children.

Do not store above 30°C.

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

Do not use Silosin 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.

Do not use any Silosin pack that is damaged or shows signs of tampering.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Silosin contains

Silosin 8 mg

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

• The other ingredients are pregelatinised maize starch, mannitol (E421), magnesium stearate, sodium laurylsulfate, gelatin, titanium dioxide (E171).

Silosin 4 mg

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

• The other ingredients are pregelatinised maize starch, mannitol (E421), magnesium stearate, sodium laurylsulfate, gelatin, titanium dioxide (E171), yellow iron oxide (E172).

What Silosin looks like and contents of the pack

Silosin 8 mg are white, opaque, hard gelatin capsules, imprinted in black "ALG" on one part and "S8" on the other.

Silosin 4 mg are yellow, opaque, hard gelatin capsules, imprinted in black "ALG" on one part and "S4" on the other.

Silosin is available in packs containing 5, 10, 20, 30, 50, 90, 100 capsules.

Not all pack sizes and strengths may be marketed.

This is a medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicine, their benefits and risks.

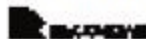
- Do not by yourself interrupt the period of treatment prescribed.

- Do not repeat the same prescription without consulting your doctor.

- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab pharmacists

Developed, manufactured and sold by
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P14740-01-RK
Rev. No. 10/2015