

## **PACKAGE LEAFLET: Information for the patient**

### **SILOCURE**

Hard capsules – 4 mg, 8 mg

(Silodosin)

**Read all of this leaflet carefully before you start using 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 Silocure is and what it is used for
2. What you need to know before you take Silocure
3. How to take Silocure
4. Possible side effects
5. How to store Silocure
6. Other information

### **1. WHAT SILOCURE IS AND WHAT IT IS USED FOR**

#### **What Silocure is**

Silocure contains the active substance silodosin which belongs to a group of medicines called  $\alpha_{1A}$ -adrenoreceptor blockers.

Silocure 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 Silocure is used for**

Silocure 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 SILOCURE**

**Do not take Silocure** 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 or pharmacist before taking Silocure:

- 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 Silocure. 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 Silocure when undergoing cataract surgery.
- If you have ever fainted or felt dizzy when suddenly standing up, please inform your doctor before taking Silocure.

Dizziness when standing up and occasionally fainting may occur when taking Silocure, 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 Silocure, 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 Silocure with caution and possibly with a lower dose (see section 3 “How to take Silocure”). If you have severe kidney problems, you should not take Silocure.

- 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 Silocure. Silocure does not treat prostate cancer.
- The treatment with Silocure 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 Silocure. 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 Silocure**

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  $\alpha_1$ -blockers, such as prazosin or doxazosin) as there may be the potential risk that the effect of these medicines is increased whilst taking Silocure;
- **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 Silocure;
- **medicines used for treating problems in getting or keeping an erection** (such as sildenafil or tadalafil), since the concomitant use with Silocure might lead to a slight decrease in blood pressure;
- **medicines for epilepsy or rifampicin** (a medicine to treat tuberculosis), since the effect of Silocure may be reduced.

**Fertility**

Silocure may reduce the amount of sperm, and so could temporarily affect your ability to father a child. If you are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**

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

**Important information about some of the excipients of Silocure**

The hard capsule Silocure 8 mg, contains the azo colouring agent Tartrazine (E102). It may cause allergic reactions.

**3. HOW TO TAKE SILOCURE**

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 Silocure 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.

**Patients with kidney problems**

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

**If you take more Silocure 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 Silocure**

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 Silocure**

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 Silocure. 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.

Silocure 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 Silocure.

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 “Warnings and precautions”).

### **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 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 (see also above, in this section).

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

**5. HOW TO STORE SILOCURE**

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 carton and blister.

Do not store above 25°C.

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

## **6. OTHER INFORMATION**

### **What Silocure 4 mg hard capsules contain**

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

The excipients are:

*Capsule content:* pregelatinised starch, mannitol, sodium laurylsulfate, magnesium stearate.

*Capsule body:* gelatin, titanium dioxide.

### **What Silocure 8 mg hard capsules contain**

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

The excipients are:

*Capsule content:* pregelatinised starch, mannitol, sodium laurylsulfate, magnesium stearate.

*Capsule body:* gelatin, titanium dioxide, tartrazine – FD&C yellow 5.

### **Pack content**

Silocure is available in packs containing 30 capsules.

### **Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

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**This leaflet was last revised in November 2023.**