

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

**Sildazen
12.5 mg/actuation, oral suspension**

Active ingredient

1 ml of suspension contains 25 mg sildenafil (as citrate)

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Sildazen is intended for treatment of erectile dysfunction in adult men (impotence).

This happens when a man cannot get, or keep a firm erection suitable for satisfactory sexual activity.

Therapeutic group: phosphodiesterase type 5 inhibitor (PDE5).

Sildazen works by dilating the blood vessels in your penis, allowing blood to flow into it when you are sexually stimulated. Sildazen will only help you to get an erection if you are sexually stimulated.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to sildenafil or to any of the other ingredients in this medicine (see section 6).
- You are taking medicines called nitrates, as the combination may lead to a dangerous fall in your blood pressure. Tell your doctor if you are taking any of these medicines, which are often given for relief of angina pectoris (chest pain).
- You are using any of the medicines known as nitric oxide donors such as amyl nitrite ("poppers"), such as certain medicines for treatment of angina pectoris (chest pain), as the combination may lead to a dangerous fall in your blood pressure.
- You are taking riociguat. This medicine is used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs caused by clots). PDE5 inhibitors, such as Sildazen, have been shown to increase the hypotensive (blood pressure reduction) effect of this medicine.
- You have a severe heart or liver problem.
- You have recently had a stroke or a heart attack, or if you have low blood pressure.
- You have a rare inherited eye disease (such as retinitis pigmentosa).
- You have ever had impairment of vision due to non-arteritic anterior ischaemic optic neuropathy (NAION).

Special warnings about using this medicine

Before treatment with Sildazen, tell your doctor if:

- You have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow).
- You have a deformity of your penis or Peyronie's Disease.

- You have problems with your heart. Your doctor should check whether your heart can take the additional strain of having sex.
- You currently have a stomach ulcer or bleeding problems (such as haemophilia).

Additional warnings

If you experience sudden decrease or loss of vision, stop taking Sildazen and contact your doctor immediately.

You should not use Sildazen with any other oral or local treatments for erectile dysfunction.

You should not use Sildazen with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitor.

You should not take Sildazen if you do not have erectile dysfunction.

You should not take Sildazen if you are a woman.

There are special considerations for patients with kidney or liver problems. You should tell your doctor if you have kidney or liver problems. Your doctor may decide to reduce your dose.

Children and adolescents

Sildazen is not intended for use under the age of 18.

There is no information about the safety and effectiveness of use of this medicine in children and adolescents under the age of 18.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

Medicines containing sacubitril/valsartan, used to treat heart failure.

Sildazen may interfere with the activity of some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell your doctor, pharmacist or nurse that you are taking Sildazen and when you took it. Do not take Sildazen with other medicines unless your doctor advises you to.

You should not take Sildazen if you are taking medicines called nitrates, which are intended to treat chest pain, angina pectoris, as the combination of these medicines may lead to a dangerous fall in your blood pressure. Always tell your doctor, pharmacist or nurse if you are taking any of these medicines, which are often used for the relief of angina pectoris (chest pain).

You should not take Sildazen if you are taking medicines known as nitric oxide donors such as amyl nitrite ("poppers"), as the combination of these medicines may lead to a dangerous fall in your blood pressure.

If you are taking medicines known as protease inhibitors, such as those used for the treatment of HIV, your doctor may start you on the lowest dose (25 mg = 2 actuations) of Sildazen.

Some patients who take an alpha-blocker, a medicine used for the treatment of high blood pressure or prostate enlargement, may experience dizziness or light-headedness, which may be caused by a fall in blood pressure upon sitting or standing up quickly.

Some patients have experienced these symptoms when taking Sildazen with alpha-blockers. This is most likely to happen within 4 hours of taking Sildazen.

To reduce the chance that these symptoms appear, you should be treated with a regular daily dose of your alpha-blocker before you start treatment with Sildazen. Your doctor may start with a lower dose (1 ml equivalent to 25 mg sildenafil, 2 actuations) of Sildazen.

Using this medicine and food

Sildazen can be taken with or without food. However, you may find that Sildazen takes a little longer to start working if you take it with a heavy meal.

Using this medicine and alcohol consumption

Drinking alcohol can temporarily impair your ability to get an erection. Therefore, to get the maximum benefit from the medicine, you are advised not to drink large amounts of alcohol before taking Sildazen.

Pregnancy, breast-feeding and fertility

You should not take Sildazen if you are a woman.

Driving and using machines

Sildazen can cause dizziness and can affect vision. You should be aware of how you react to Sildazen before you drive or use machinery.

Important information about some of this medicine's ingredients

This medicine contains 1 mg of sodium benzoate per 1 ml of suspension.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The recommended starting dose is 2 ml equivalent to 50 mg (4 actuations). Each actuation delivers 0.5 ml of suspension, a volume which contains 12.5 mg of sildenafil.

Number of actuations	Quantity of suspension delivered	Quantity of sildenafil
2	1 ml	25 mg
4	2 ml	50 mg
8	4 ml	100 mg

The maximum daily dose is 4 ml, equivalent to 100 mg (8 actuations).

You should not take Sildazen more than once a day.

Do not exceed the recommended dose.

You should not take Sildazen with other medicines that contain sildenafil.

You should take Sildazen about one hour before you plan to have sex. Sildazen is intended for oral administration only.

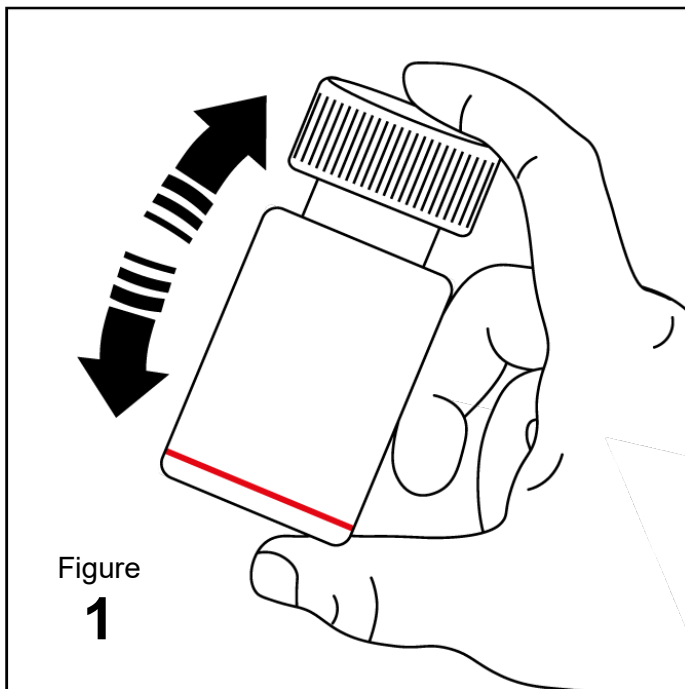
Not intended for nasal administration or application to the skin (topical use).

For correct use, please follow the instructions for administration.

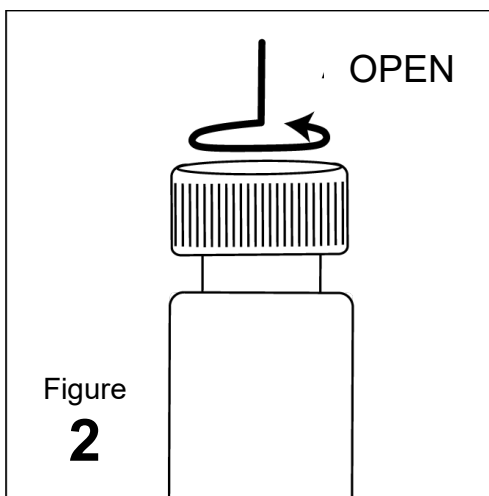
Always use the pump supplied in Sildazen package.

Method of administration

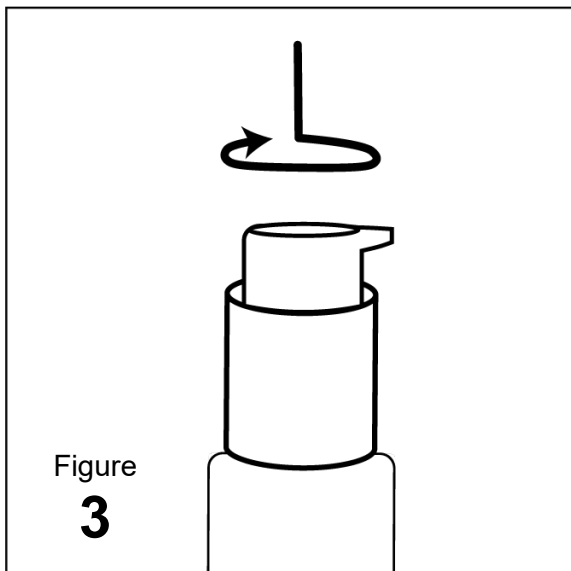
1. Shake the bottle vigorously approximately 20 seconds to ensure that no drug precipitate is observed in the bottle before each use. See figure 1.



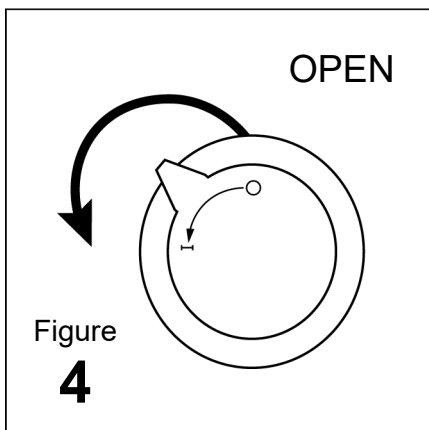
2. The child-resistant screw cap should be removed by pushing it down firmly and turning it anticlockwise. See figure 2



3. The dosage pump has to be placed on top of the bottle sliding the plastic tube carefully into the bottle. Then the dosing pump needs to be held onto the neck of the bottle and screwed clockwise until it is firmly attached. See figure 3.



4. Twist the dosage pump into open position. See Figure 4.

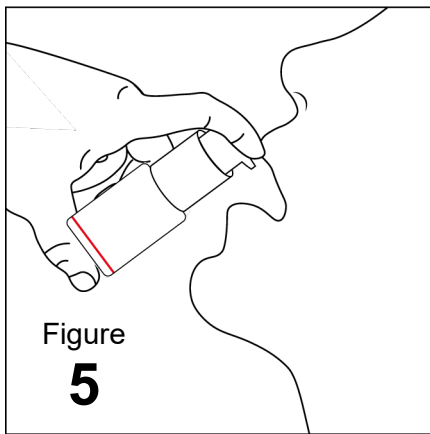


5. Before every use (including first-time use): Activate the pump three times to prepare (prime) the dosage pump, discard any product released during this activation into an absorbent material. The pump is now ready to be used and each metered spray delivers an average of 12.5 mg of sildenafil.

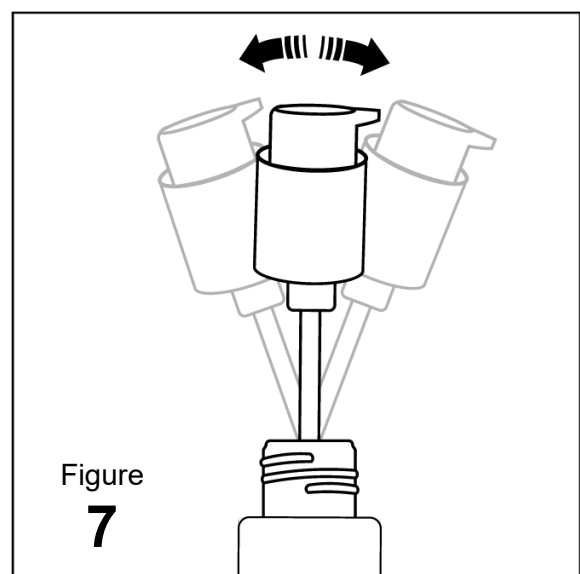
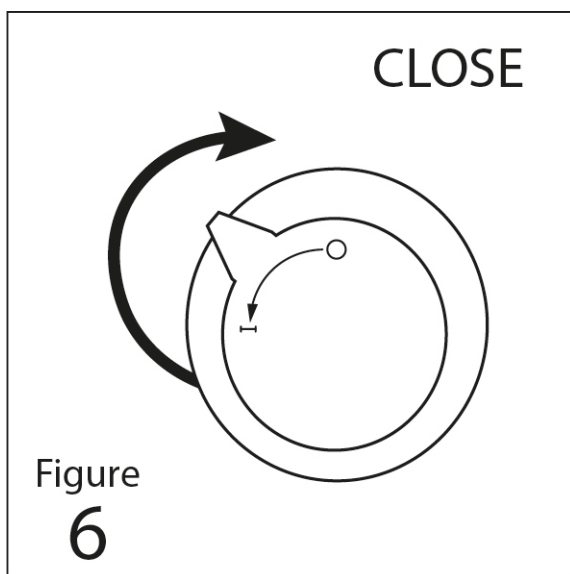
A failure in this priming process may lead to a lower dose when used.

Discard the bottle when the drug level is below the red line.

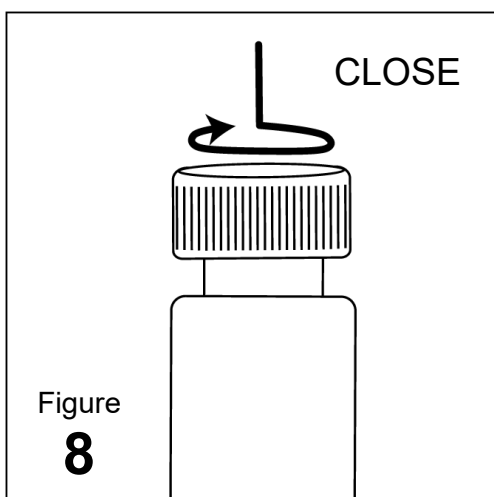
6. Tilt your head back a little. Place the pump in your mouth. Press the dosage pump as many times as required, according to the dose prescribed by your doctor and apply the suspension on the tongue and swallow the suspension immediately with saliva. Avoid direct contact between the end of the dosage pump and inside the mouth and tongue. See figure 5.



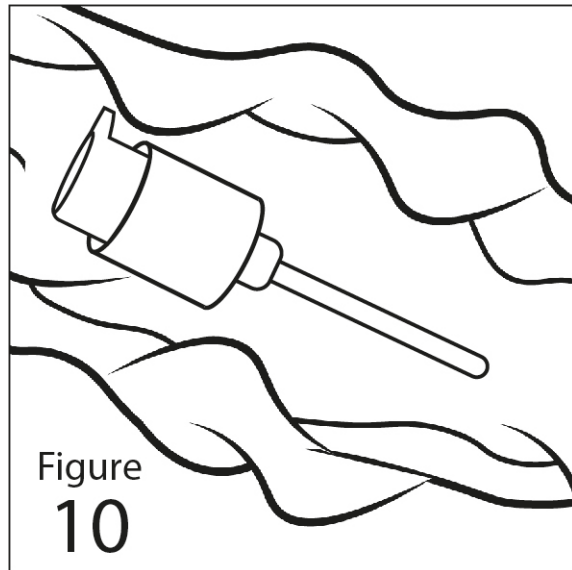
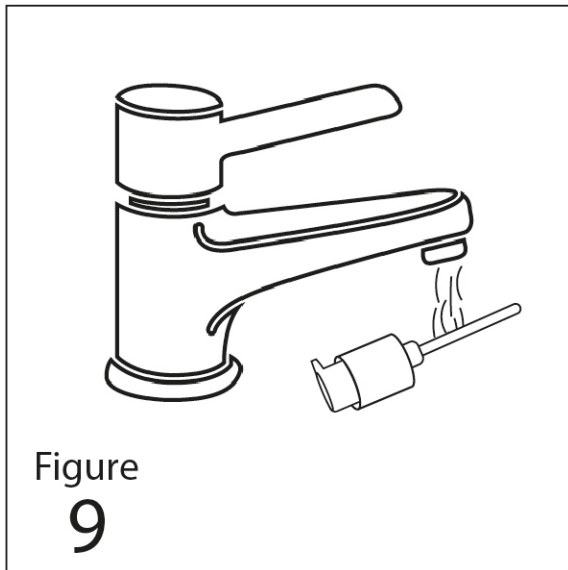
7. Twist the dosage pump to closed position (Figure 6) and remove the pump after dripping it against the internal walls of the bottle by unscrewing anticlockwise (Figure 7).



8. The child resistant screw cap should be put back on the bottle to close it immediately after each use (Figure 8).



9. Wash completely the dosage pump with water, ensuring that no product or water remains in the pump by activating the pump several times into an absorbent material. Allow it to dry thoroughly before the next use. See figure 9 and figure 10.



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

NOTE FOR PATIENTS – These instructions for use require priming before each dose and washing the dosing pump. Therefore, the bottle will contain a final average deliverable volume of 20 ml of the oral suspension.

Sildazen will only help you to get an erection if you are sexually stimulated. The amount of time Sildazen takes to work varies from person to person, but it normally takes between half an hour and one hour. Sildazen may take longer to work if you take it with a heavy meal. If Sildazen does not help you get an erection, or if your erection does not last long enough for you to complete sexual intercourse, tell your doctor.

If you took an overdose Sildazen

You may experience an increase in side effects and their severity. Doses above 100 mg do not increase the efficacy.

You should not exceed the dose of Sildazen recommended by the doctor.

Contact your doctor if you have taken more Sildazen than you should.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicines. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Sildazen may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

The side effects reported in association with the use of Sildazen are usually mild to moderate and of a short duration.

If you experience any of the following serious side effects stop taking Sildazen and seek medical help immediately:

- An allergic reaction - this reaction is uncommon (may affect up to 1 in 100 people). Symptoms include wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.

- Chest pains - this effect is uncommon.
If this appears during or after sexual intercourse:
 - Get into a semi-sitting position and try to relax.
 - Do not use nitrates to treat your chest pain.
- Prolonged and sometimes painful erections - this effect is rare (may affect up to 1 in 1,000 people).
If you have an erection which lasts for more than 4 hours, you should contact your doctor immediately.
- A sudden decrease or loss of vision - this effect is rare.
- Serious skin reactions - this effect is rare.
Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, as well as fever.
- Seizures or fits - this effect is rare.

Additional side effects

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

Headache

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

Nausea, facial flushing, hot flush (symptoms include a sudden feeling of heat in your upper body), indigestion, abnormal colour perception, blurred vision, visual disturbance, stuffy nose and dizziness.

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

Vomiting, skin rash, eye irritation, red eyes, eye pain, seeing flashes of light, visual brightness, light sensitivity, watery eyes, pounding heartbeat, rapid heartbeat, high blood pressure, low blood pressure, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, dry mouth, blocked or stuffy sinuses, inflammation of the lining of the nose (symptoms include runny nose, sneezing and stuffy nose), upper abdominal pain, gastro-oesophageal reflux disease (symptoms include heartburn), presence of blood in urine, pain in the arms or legs, nosebleed, feeling hot and feeling tired.

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

Fainting, stroke, heart attack, irregular heartbeat, temporary decreased blood flow to parts of the brain, feeling of tightening of the throat, numb mouth, bleeding at the back of the eye, double vision, reduced sharpness of vision, abnormal sensation in the eye, swelling of the eye or eyelid, small particles or spots in your vision, seeing halos around lights, dilation of the pupil of the eye, discolouration of the white of the eye, penile bleeding, presence of blood in semen, dry nose, swelling of the inside of the nose, feeling irritable and sudden decrease or loss of hearing.

From post marketing experience of sildenafil, cases of unstable angina (a heart condition) and sudden death have been reported rarely. Of note, most, but not all, of the men who experienced these side effects had heart problems before taking this medicine. It is not possible to determine whether these side effects were directly related to sildenafil.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/bottle. The expiry date refers to the last day of that month.
- **Storage conditions**
Store this medicine below 30°C.
Once opened, the suspension may be used for 12 months, but no later than the expiry date of the medicine.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist about how to throw away medicines you no longer use. This will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Masking flavour SC241160, peppermint flavour 501500 TP0504, hypromellose (15cp), anhydrous citric acid, xanthan gum, sucralose, acesulfame potassium (E-950), sodium benzoate, purified water.

What the medicine looks like and contents of the pack:

The suspension is white-cream with a peppermint aroma.

Packaged in a 30 ml bottle equipped with a pump and a child resistant cap.

Registration holder's name and address: Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761

Manufacturer's name and address:

FARMALIDER S.A., C/ARAGONESES, 2 28108 ALCOBENDAS - MADRID, SPAIN

Revised in June 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 170-66-36152-00