

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

**Name of the medicine, its form and strength**

**SLIDER**

**Film-coated tablets**

**Sildenafil (as citrate) 20 mg**

A list of the inactive and allergenic ingredients in the preparation are detailed in section 6.

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

The medicine is intended for adults above the age of 18.

**1. WHAT IS THE MEDICINE INTENDED FOR?**

For treatment of pulmonary hypertension in patients over the age of 18.

**Therapeutic group:**

Phosphodiesterase 5 enzyme (PDE-5) inhibitors.

**2. BEFORE USING THE MEDICINE**

**❗ Do not use the preparation if:**

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (detailed in section 6).
- You are taking medicines containing nitrates or nitric oxide donors such as amyl nitrite. These medicines are generally given for treatment of angina pectoris. **Slider** may significantly increase the effect of these medicines.
- You are taking riociguat, a medicine used for treating pulmonary hypertension, since **Slider** can increase the effect of this medicine.
- You have recently had a stroke, heart attack, if you have a severe liver disease or if you have particularly low blood pressure (<90/50 mmHg).
- You are taking antifungal medication, such as ketoconazole or itraconazole, or medicines that contain ritonavir (for the treatment of AIDS).
- You have suffered in the past from a loss of vision because of a problem of blood flow to the optic nerve known as non-arteritic anterior ischemic optic neuropathy (NAION).

**Special warnings regarding use of the medicine:**

**⚠ Before treatment with Slider, tell the doctor if:**

- You are suffering from a disease caused by a blocked or narrow vein in the lungs.
- You are suffering from a severe heart problem or if you have a blood pumping problem within the heart chambers.
- You have high blood pressure in the pulmonary blood vessels.

- You have low blood pressure while at rest.
- You are suffering from excessive fluid loss (dehydration), which can occur when you sweat a lot, or if you are not drinking enough liquids, or you are suffering from an illness accompanied by a fever, vomiting or diarrhea.
- You are suffering from a rare hereditary eye disease (such as retinitis pigmentosa).
- You are suffering from sickle cell anemia, from cancer of the blood cells (leukemia), from cancer of the bone marrow (multiple myeloma) or from any disease or deformity of the male sex organ.
- You are suffering from an active stomach ulcer, clotting problems and excessive bleeding (e.g., hemophilia) or repetitive nosebleeds.
- You are taking medication for impotence.

**Patients with kidney or liver problems**

Inform the doctor if you are suffering from kidney or liver problems, as it may be necessary to adjust your dosage of the medication.

**⚠ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** Especially, if you are taking:

- Medicines containing nitrates or nitric oxide donors such as amyl nitrite. These medicines are generally given to treat angina pectoris (see Section 2).
- Riociguat.
- Medicines for treating pulmonary hypertension (such as bosentan, iloprost).
- Preparations containing St. John's Wort (herbal medicinal product), rifampicin (for treatment of bacterial infections), carbamazepine, phenytoin and phenobarbital (among others for treatment of epilepsy).
- Blood thinners (such as warfarin).
- Medicines containing erythromycin, clarithromycin, telithromycin (antibiotics), saquinavir (for HIV) or nefazodone (for depression), as it may be necessary to adjust the dosage of the medicine for you.
- Medicines from the alpha-blockers group (such as doxazosin) for treatment of hypertension or prostate problems, due to a concern for a decrease in your blood pressure (manifested by dizziness).

**⚠ Use of the medicine and food:**

The medicine may be taken with or without food.

Do not consume grapefruit juice during the course of treatment with the medicine.

**⚠ Pregnancy and breastfeeding:**

Before taking the medicine, consult with the doctor if: you are pregnant or breastfeeding, could be pregnant, or are planning to become pregnant or to breastfeed.

Do not use this preparation during pregnancy or when breastfeeding unless the doctor has instructed otherwise.

Use contraception during treatment.

The medicine passes into the mother's milk only in very small quantities, and it is therefore not expected to harm your baby.

**⚠ Driving and operating machinery:**

Use of the medicine may cause dizziness and affect vision and therefore caution should be exercised when driving a car and operating dangerous machinery.

**3. HOW SHOULD YOU USE THE MEDICINE?**

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation. This medicine is intended for adults above the age of 18. The safety and efficacy of the medicine in children have not been proven.

The dosage and treatment regimen will be determined by the doctor only.

**The usual dosage is generally:** One 20 mg tablet three times a day, every 6-8 hours.

Swallow the medicine with water.

Do not halve the tablet. There is no information regarding crushing or chewing the tablet.

**Do not exceed the recommended dose.**

**If you took an overdose, or if a child has accidentally swallowed the medicine,** refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

**If you forgot to take this medicine at the required time,** take a dose as soon as you remember, however, under no circumstances should you take a double dose!

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

**If you stop taking the medicine:** Abrupt discontinuation of treatment with **Slider** may worsen the symptoms from which you are suffering. Do not stop treatment unless instructed by the doctor. It is possible the doctor will decide to discontinue treatment gradually.

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

**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

**4. SIDE EFFECTS:**

As with any medicine, use of **Slider** may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

**Stop treatment and refer to a doctor immediately in case of:** Sudden complete or partial loss of vision, either temporary or permanent, in one or both eyes (unknown frequency), an erection lasting continuously for more than 4 hours. A prolonged erection, sometimes accompanied by pain, has been reported after use of sildenafil (unknown frequency).

**Very common side effects - effects that occur in more than one user in ten:** Headache, facial flushing, indigestion, diarrhea and pain in the extremities.

**Common side effects - effects that occur in 1-10 users in 100:** Inflammation under the skin, flu-like symptoms, sinusitis, reduced number of red blood cells (anemia), fluid retention, sleep disturbances, anxiety, migraine, tremor, stinging and burning sensation, decrease in sense of touch, bleeding at the back of the eye, disturbed or blurred vision, sensitivity to light, difficulty in distinguishing between colors, irritation and redness in the eyes, dizziness, bronchitis, nosebleed, nasal congestion, cough, runny nose, inflammation of the stomach and/or the intestines, heartburn,

hemorrhoids, digestive system disturbances and bloating, dry mouth, hair loss, redness of the skin, night sweats, muscle pain, back pain and increased body temperature.

**Uncommon side effects - effects that occur in 1-10 users in 1,000:** Decreased sharpness of vision, double vision, uncomfortable sensation in the eye, penile bleeding, presence of blood in the semen and/or urine and breast enlargement in men.

**Side effects of unknown frequency (side effects whose frequency has not yet been determined):** Skin rash, sudden decrease or loss of hearing, and decreased blood pressure.

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

Side effects can be reported to the Ministry of Health by clicking on the link "[Reporting Side Effects of Drug Treatment](#)" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects.

Alternatively, side effects may be reported to "[Unipharm Ltd.](#)".

**5. HOW SHOULD THE MEDICINE BE STORED?**

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage Conditions:** Store at a temperature below 25°C and protected from light.

**6. FURTHER INFORMATION**

In addition to the active ingredient, the medicine also contains: Dicalcium Phosphate Dihydrate, Microcrystalline Cellulose, Povidone, Croscarmellose Sodium, Magnesium Stearate, Opadry (Blue, Purple, Red).

**What the medicine looks like and the contents of the package:** **Slider** tablets are film-coated, round, biconvex and colored purple. **Slider** tablets are packed in blister trays within a carton. In every pack there are either 5, 7, 10, 14, 15, 20 or 90 tablets. It is possible that not all pack sizes are available.

License holder: Unipharm Ltd., P.O.Box 21429 Tel Aviv, 6121301.

Manufacturer and address: Trima Ltd., Kibbutz Maabarot.

This leaflet was checked and approved by the Ministry of Health in August 2014, and updated in accordance with Ministry of Health regulations in June 2018.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 149 17 33602 00

