

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

The medicine is dispensed with
a doctor's prescription only

TARIM 25; 50; 100

Film-coated tablets

Composition:

Each film-coated **Tarim 25** tablet contains:
Sildenafil (as citrate) 25 mg

Each film-coated **Tarim 50** tablet contains:
Sildenafil (as citrate) 50 mg

Each film-coated **Tarim 100** tablet contains:
Sildenafil (as citrate) 100 mg

For inactive ingredients: see section 6: "Further Information".

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 the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The medicine is intended for adults above the age of 18. The medicine is not intended for women.

1. WHAT IS THE MEDICINE INTENDED FOR?

This medicine belongs to a therapeutic group of phosphodiesterase 5 (PDE5) enzyme inhibitors and it is intended for the treatment of erectile dysfunction among men.

The preparation is not intended for women. The preparation is intended for adults above the age of 18.

2. BEFORE USING THE MEDICINE

❗ Do not use the preparation if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine - also see section 6: "Further Information".
- You intermittently or regularly take organic nitrates, organic nitrites or nitric oxide donors in any form (that are often given to relieve angina pectoris). If you are not sure, ask the doctor or pharmacist. This combination may decrease your blood pressure dangerously.
- You have recently suffered a stroke or heart attack, or if you suffer from low blood pressure.
- You suffer from severe heart or liver diseases.
- You suffer from rare inherited eye diseases, such as retinitis pigmentosa.
- You suffered in the past from loss of vision due to a condition called non-arteritic anterior ischemic optic neuropathy.

Before treatment with Tarim, inform the doctor if:

- you are suffering, or have suffered in the past, from impaired function of: the heart and/or blood vessels, the digestive system (e.g., ulcer), the blood system (e.g., coagulation problems such as hemophilia, leukemia), from a deformity of the sexual organ or from Peyronie's disease, from conditions that may cause prolonged erection, (e.g.: sickle cell anemia, multiple myeloma), from liver disease (e.g., cirrhosis),

severe renal insufficiency, hypotension (blood pressure below 90/50), high blood pressure (blood pressure above 170/110).

- you are sensitive to any food or medicine.

Special warnings regarding use of the medicine:

- A person who has taken **Tarim** and requires any type of medical attention must report immediately to the attending medical team that he has taken this medicine and when he has taken it, in order to prevent a situation in which he will be treated with nitrates or other vasodilators.
- Do not use this medicine together with other medicines that treat erectile dysfunction, including local treatment.
- Patients above the age of 65 will be treated with a lower starting dosage.
- if you experience loss or decrease of vision - stop the treatment and refer to the doctor immediately.

❗ Use in children and adolescents:

This medicine is not intended for use in children and adolescents below the age of 18.

❗ Use in patients with impaired liver/kidney function:

Inform the doctor if you have liver or kidney function problems. The doctor may decide on a lower dosage of the medicine for you.

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is especially important to tell the doctor or pharmacist if you are taking:

- Organic nitrates, organic nitrites or nitric oxide donors in any form (usually used to relieve symptoms of angina pectoris, such as chest pains) (see section "Do not use the preparation if") - do not concomitantly use **Tarim** with these preparations for fear of an extreme reduction in blood pressure.
- **Medicines that may increase the levels of Tarim in the blood:** ketoconazole (antifungal), cimetidine (for gastric ulcer), erythromycin (antibiotic), HIV protease inhibitors (for treatment of AIDS), such as: saquinavir, ritonavir.
- Doxazosin or other medicines from the alpha-blockers group (for treatment of hypertension or prostate gland problems) - combination therapy with **Tarim** and these medicines may cause hypotension and dizziness.
- Other preparations for treatment of erectile dysfunction, including local treatment.

❗ Taking Tarim and food:

The medicine can be taken without regard to meals. However, it may take longer for the medicine to start working when it is taken after a heavy meal.

❗ Use of the medicine and alcohol consumption:

Drinking alcohol may have a temporary negative effect on sexual function; it is therefore advised not to drink excessive amounts of alcohol before taking the medicine.

❗ Pregnancy and breastfeeding:

The preparation is not intended for women.

❗ Driving and use of machines:

Use of this medicine may cause dizziness and affect vision. Be sure to ascertain how you react to the medicine before driving a car, operating dangerous machinery and engaging in any activity that requires alertness.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally: one tablet per day.

Do not take more than one tablet per day. **Do not exceed the recommended dose.**

Swallow the medicine with a glass of water, approximately one hour before sexual intercourse. Do not chew! **Tarim 100** - if necessary, the tablet can be halved for immediate use.

Tarim only acts when there is sexual stimulation. The duration of time until it starts working varies from one person to another, but usually takes between one half to one hour. More time may be necessary when the medicine is taken with a heavy meal.

If you feel that the medicine is not effective, or is not effective enough, tell the doctor.

If you have taken a higher dosage, you may suffer from an increase in the occurrence and severity of side effects. Dosages above 100 mg do not increase the effectiveness of the medicine.

If you accidentally take a higher dosage or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

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 **Tarim** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Discontinue use and refer to the doctor immediately if you feel any of the following side effects:

- sudden loss of vision in one eye or both eyes - stop taking the medicine immediately and refer to the doctor (a side effect that occurs rarely).
- sudden decrease in hearing or loss of hearing (a side effect that occurs rarely).
- allergic reaction (uncommon side effect), including difficulty breathing (sometimes with a wheezing attack), dizziness, swelling of the eyelids, face, lips or throat.
- prolonged and sometimes painful erection (above 4 hours) (a side effect that occurs rarely).
- In the event that you experience chest pain during or after sexual intercourse (uncommon side effect), sit in a semi-reclining position and try to relax. Never take nitrates for chest pain! Refer to a doctor immediately.
- Severe skin reactions (a side effect that occurs rarely). Symptoms may include severe peeling and swelling of the skin, fever, blisters in the mouth, sexual organ and in the area of the eyes.
- Convulsions or seizures (side effects that occur rarely).

Additional side effects:

Very common side effects (occur in more than one in 10 patients): Headache.

Common side effects (occur in 1-10 in 100 patients): flushing, hot flushes, digestive system disturbances, vision disturbances, effect on seeing colors, blurred vision, nasal congestion, dizziness.

Uncommon side effects (occur in 1-10 in 1,000 patients): Vomiting, skin rash, intraocular bleeding, irritation in the eyes, eye redness, eye pain, seeing light flashes, visual brightness, sensitivity to light, tearing eyes, palpitations, rapid heart rate, high blood pressure, low blood pressure, muscle pain, sleepiness, reduced sensation, vertigo, blocked or stuffy sinuses, inflammation in the nose (symptoms include runny nose, sneezing and nasal congestion), upper abdominal pain, esophageal reflux disease (symptoms include heartburn), ringing in the ears, nausea, dry mouth, blood in the urine, arm or leg pain, nosebleed, feeling hot, tiredness.

Rare side effects (occur in 1-10 in 10,000 patients): fainting, stroke, heart attack, irregular heart rate, temporary decrease in blood flow to parts of the brain, feeling of constriction in the throat, numb mouth, bleeding in the back part of the eye, double vision, reduced visual acuity, swelling of the eye or eyelid, seeing small particles or spots, seeing a halo around lights, dilation of the pupil, discoloration of the white of the eye, penile bleeding, blood in semen, dry nose, swelling in the nose, agitation, sudden decrease or loss of hearing.

Additional side effects reported post-marketing: angina pectoris and sudden death have been reported rarely. In most cases (but not in all), the patients had heart problems before taking this medicine. It is not possible to determine whether these events occurred as a result of taking the medicine.

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

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants 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.
- Store the medicine at a temperature below 25°C in a dry place 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:

Tarim are round (**Tarim 25**) or oval (**Tarim 50** and **Tarim 100**) film-coated tablets, biconvex and colored purple.

Registration holder: Unipharm Ltd., P.O.B. 21429, Tel-Aviv 6121301.

Manufacturer and address: Trima Ltd., Kibbutz Maabarot.

This leaflet was checked and approved by the Ministry of Health in February 2015.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Tarim 25: 149 14 33581 00

Tarim 50: 149 15 33582 00

Tarim 100: 149 16 33583 00

 **unipharm Ltd.**