

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

The medicine is dispensed with a doctor's prescription only

TARIM 50; 100

Film-coated tablets

Composition:

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 the list of inactive and allergenic ingredients in the preparation, see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the 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 to treat you. 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 over the age of 18. The medicine is not intended for women.

1. WHAT IS THE MEDICINE INTENDED FOR?

For the treatment of impotence – erection disturbances.

Therapeutic group:

PDE5 enzyme inhibitor, causes dilation of blood vessels, thereby improving the blood flow into the penis during sexual stimulation.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine – see section 6 "Further information".
- You intermittently or regularly take organic nitrates, organic nitrites or nitric oxide donors, such as amyl nitrite, in any form (such as certain medicines to treat angina pectoris).
- You are concomitantly taking guanylate cyclase stimulators, such as riociguat (for treating pulmonary hypertension).
- You suffer from a severe liver or heart disease.
- You have recently suffered a stroke or heart attack, or if you suffer from low blood pressure.
- You suffer from a certain rare inherited eye disease (such as retinitis pigmentosa).

- You suffer, or have suffered in the past, from loss of vision due to non-arteritic anterior ischemic optic neuropathy (NAION).

Special warnings regarding use of the medicine Before treatment with Tarim, inform the doctor if:

- You suffer from sickle cell anemia (a disease of red blood cells), multiple myeloma (cancer of the bone marrow) or leukemia (cancer of the blood cells).
- You suffer from penis deformity or from Peyronie's disease (scoliosis of the penis).
- You have problems with your heart. The doctor will check whether your heart can bear the additional strain associated with sexual intercourse.
- You suffer from a stomach ulcer or bleeding problems such as hemophilia.
- You experience a sudden decrease or loss of vision; stop the treatment and contact a doctor immediately.
- Do not take **Tarim** if you do not suffer from impotence (erectile dysfunction).
- Do not take **Tarim** if you are a woman.

Kidney or liver patients

If you have a kidney or liver disease, the doctor may decide on a lower dosage for you.

Children and adolescents

The medicine is not intended for use under the age of 18.

Tests and follow-up

Before taking the medicine, the patient must undergo a comprehensive medical examination to ensure that the treatment is suitable for him and that he does not suffer from cardiovascular problems (heart and blood vessels), since sexual activity in itself involves a certain degree of cardiac effort.

Drug interactions

A person who has taken **Tarim** and requires any type of medical treatment **must report immediately** to the attending medical team that he has taken this medicine, in order to prevent a situation in which he will be treated with nitrates or other vasodilators.

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:

Tarim in combination with other medicines, especially medicines intended to treat chest pain (angina pectoris), may be harmful. In the event of a medical emergency, you must inform the doctor, nurse or pharmacist that you have taken **Tarim** and when you took it. Do not use **Tarim** in combination with other medicines unless the doctor has told you that you can. Do not use **Tarim** if you are taking the following medicines:

- Medicines called nitrates, as the combination with these types of medicines may lead to a dangerous decrease in blood pressure. Consult the doctor if you are taking any of these medicines, which are usually used for the treatment of angina pectoris (chest pain).
- Medicines called nitric oxide donors such as amyl nitrite, as this combination may also lead to a dangerous decrease in blood pressure.
- Other medicines (oral or topical administration) for treating impotence (erectile dysfunction) – the combination with **Tarim** is forbidden.
- Riociguat or other medicines for the treatment of pulmonary hypertension – the combination with **Tarim** is forbidden.

Additional medicines

- Cimetidine (to reduce stomach acidity), ketoconazole (antifungal), erythromycin (antibiotic).
- HIV protease inhibitors for the treatment of AIDS (such as saquinavir, ritonavir), since they may increase the concentration of **Tarim** in the blood. The doctor may prescribe you the lowest dosage.
- Medicines of the alpha-blockers group, such as doxazosin (for the treatment of hypertension or prostate enlargement) – due to the concern of a decrease in blood pressure. Combination of this medicine with **Tarim** may cause light-headedness or dizziness, which is caused by low blood pressure upon sitting or standing up quickly. This is most likely to happen within 4 hours after taking **Tarim**. The doctor may prescribe you the lowest dosage.
- Medicines containing sacubitril/valsartan, used to treat heart failure.

Use of the medicine and food

The medicine can be taken with or without food; however, the onset of the effect of the medicine may be delayed when it is taken after a heavy meal.

Use of the medicine and alcohol consumption

Alcohol consumption may temporarily disrupt erection; in order to obtain maximal benefit from the medicine, it is recommended not to consume excessive amounts of alcohol before taking the medicine.

Pregnancy and breastfeeding

This medicine is not intended for women.

Driving and operating machinery

Tarim may cause dizziness and affect vision. Pay attention to how you react to the medicine before driving or operating machinery.

Important information about some of the ingredients of the medicine

The medicine contains sodium. **Tarim** contains less than 1 mmol sodium (23 mg) per tablet, that is to say, it is essentially "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's

instructions. Check with the doctor or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

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

The usual dosage is generally: one tablet approximately one hour before sexual intercourse.

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

Tarim will help you to get an erection only if you are sexually stimulated. The time it takes for the medicine to start working varies from person to person, and it usually takes about half an hour to one hour. You may find that it takes the medicine longer to start working if it was taken with a heavy meal.

If you feel that the medicine is too weak or too strong for you, consult the doctor or pharmacist.

If **Tarim** does not help you to get an erection, or if the erection achieved does not last long enough for you to complete full sexual intercourse, consult the doctor. Swallow the medicine with some water.

Tarim 50 – do not halve the tablet.

Tarim 100 – if necessary, the tablet can be halved for immediate use.

There is no information regarding chewing or crushing the tablet.

If you took an overdose 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.

If you took an overdose, you may experience an exacerbation in side effects and their severity. Doses above 100 mg do not increase the effectiveness of the medicine.

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.

Side effects reported with use of **Tarim** are generally mild to moderate and last for a short time.

Discontinue use and refer to the doctor immediately in case of:

- An allergic reaction – uncommon (may affect up to 1 person in 100); the symptoms include sudden wheezing, difficulty breathing or dizziness, swelling of the eyelids, face, lips or throat.
- Chest pain during or after sexual intercourse – uncommon; if this happens during or after sexual intercourse, sit in a semi-sitting position and try to relax. **Do not take nitrates to treat chest pain.**

• Prolonged and sometimes painful erection has been reported after using **Tarim** (rare frequency). If you experience an erection which lasts for more than 4 hours, contact a doctor immediately.

• A sudden decrease or loss of vision, rare (may affect up to 1 person in 1,000); contact a doctor immediately.

• A severe skin reaction (rare frequency) – the symptoms may include severe peeling and swelling of the skin, blisters in the mouth, genitals, around the eyes and fever.

• Fits or seizures (rare frequency).

Additional side effects:

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

Headache.

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

Dizziness, redness of the face, gastrointestinal disturbances, nasal congestion, seeing colors, blurred vision, vision disturbances, nausea, hot flushes (sudden feeling of heat in the upper part of the body).

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

Vomiting, rash, eye irritation/pain, red eyes, sensitivity to light, seeing flashes of light, visual brightness, watery eyes, rapid or pounding heartbeat, hypertension, low blood pressure, muscle pain, sleepiness, reduced sense of touch, lightheadedness (vertigo), ringing in the ears, dry mouth, congested or blocked sinuses, inflammation of the inner lining of the nose (symptoms include common cold, sneezing and nasal congestion), upper abdominal pain, gastro-esophageal reflux (symptoms include heartburn), feeling tired, presence of blood in urine, pain in the extremities, nosebleed, feeling hot.

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

Fainting, stroke, heart attack, heart rate disorders, sudden reduction or loss of hearing, temporary decrease in blood flow to parts of the brain, feeling of constriction of the throat, numb mouth, bleeding at the back of the eye, double vision, reduced visual acuity, unusual sensation in the eye, swelling of the eye or eyelid, seeing small particles or spots, seeing halos around lights, dilation of the pupils, discoloration of the white of the eye, penile bleeding, presence of blood in semen, dry nose, swelling inside the nose, irritability.

Side effects reported after marketing:

Unstable angina and sudden death have been reported rarely. Most, but not all, of the men who experienced these side effects suffered from heart problems before taking this medicine. It is impossible to determine whether these effects were directly related to the use of 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.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), which directs you to an online form for reporting side effects, or by entering the following link:

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

Additionally, you can report to "[Unipharm Ltd.](http://www.unipharm.com)".

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.

• 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 OY-L-30919 (Blue), Opadry fx-63F10239 (Purple), Opadry OY-F-2857 (Red).

The preparations contain sodium. See section 2 "Important information about some of the ingredients of the medicine".

What the medicine looks like and the contents of the package:

Tarim is packaged in trays (blisters) which are inserted into a carton package. Each package contains 1, 2, 4, 8, 10, 15, 16 tablets. Not all package sizes may be marketed.

Tarim 50 are oval, film-coated, biconvex, pearl-like, purple tablets.

Tarim 100 are oblong, film-coated, biconvex, pearl-like, purple tablets with a break line on one side.

Registration holder and address: Unipharm Ltd., P.O. Box 21429, Tel Aviv, 6121301.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

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

Tarim 50 – 149 15 33582 01

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Revised in September 2023 according to MOH guidelines.

