

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

The medicine is dispensed with a doctor's prescription only

TADALAMED 2.5 mg

Film-coated tablets

Composition:

Each tablet contains: tadalafil 2.5 mg for **"Daily"** use

TADALAMED 5 mg

Film-coated tablets

Composition:

Each tablet contains: tadalafil 5 mg for **"Daily"** use

TADALAMED 10 mg

Film-coated tablets

Composition:

Each tablet contains: tadalafil 10 mg to be used **"As needed"**

TADALAMED 20 mg

Film-coated tablets

Composition:

Each tablet contains: tadalafil 20 mg to be used **"As needed"**

Inactive and allergenic ingredients in the preparation: see Section 2, subsection "Important information about some of the ingredients in this 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 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 ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Tadalamed 2.5, 10 and 20 mg is intended for the treatment of erectile dysfunction in men.

Tadalamed 5 mg is intended for:

The treatment of erectile dysfunction in men.
The treatment of benign prostatic hyperplasia symptoms.

The treatment of men suffering from erectile dysfunction and benign prostatic hyperplasia symptoms.

Therapeutic group: Urologicals, medicines used for erection problems.

What is Tadalamed?

Tadalamed contains the active substance tadalafil, which belongs to a group of medicines called phosphodiesterase type 5 inhibitors (PDE5 inhibitors).

Erectile dysfunction is a condition in which a man cannot achieve or maintain an erect penis needed for sexual activity. Tadalamed has been shown to significantly improve the ability to obtain a hard and erect penis needed for sexual activity.

Following sexual stimulation, Tadalamed works by relaxing the blood vessels in your penis, thereby allowing the flow of blood into it.

This results in improved erectile function. Tadalamed will not help you if you do not have erectile dysfunction.

It is important to note that Tadalamed does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

Benign prostatic hyperplasia is a condition in which the prostate gland gets bigger with age. Symptoms include difficulty in starting to pass urine, a feeling of not completely emptying the bladder and a more frequent need to urinate even at night. Tadalamed improves the blood flow to and relaxes the muscles of the prostate and bladder, which may reduce the symptoms of benign prostatic hyperplasia. Tadalamed has been shown to improve these urinary symptoms approximately 1-2 weeks after starting treatment.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to tadalafil or to any of the additional ingredients contained in the medicine (see section 6).
- you are taking any form of organic nitrate or nitric oxide donor such as amyl nitrite. This is a group of preparations ("nitrates") used to treat angina pectoris ("chest pain"). Tadalamed has been shown to increase the effect of these preparations. If you are taking any form of nitrate or are uncertain, tell your doctor.
- you have a serious heart disease or you had a heart attack within the last 90 days.
- you recently had a stroke within the last six months.
- you have low blood pressure or uncontrolled high blood pressure.
- you have ever suffered from loss of vision as a result of non-arterial anterior ischemic optic neuropathy (NAION), a medical condition called "stroke of the eye".
- you are taking a medicine called riociguat. This is a medicine 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 secondary to blood clots). Phosphodiesterase type 5 inhibitors (PDE5 inhibitors), such as Tadalamed, have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are uncertain, tell your doctor.

The medicine is not intended for use below the age of 18 or by women.

Special warnings regarding use of the medicine:

Speak to your doctor before taking Tadalamed. Be aware that sexual activity carries a possible risk to patients with heart disease because it demands an increased effort from the heart.

If you have a heart problem, consult your doctor. Since benign prostatic hyperplasia and prostate cancer may have identical symptoms, your doctor will check you for prostate cancer before prescribing you treatment with Tadalamed for benign prostatic hyperplasia.

Tadalamed is not intended for the treatment of prostate cancer.

Before taking the tablets, tell your doctor if:

- you have sickle cell anemia (abnormal red blood cells).
- you have multiple myeloma (cancer of the bone marrow).
- you have leukemia (cancer of the blood cells).
- you have a deformation of your penis.
- you have a serious liver problem.
- you have a serious kidney problem.

It is not known if Tadalamed is effective in patients who have had:

- pelvic surgery.
- partial or complete removal of the prostate gland in which nerves of the gland are cut.

If you experience a sudden decrease/loss of vision, stop using Tadalamed and refer to your doctor immediately.

Reduced hearing or sudden hearing loss has been noted in some patients who took tadalafil. Although use of tadalafil cannot be directly linked to this effect, if you experience reduced hearing or sudden hearing loss, stop using Tadalamed and refer to your doctor immediately.

Children and adolescents

This medicine is not intended for children and adolescents under 18 years of age.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist about it.

Do not take Tadalamed if you are taking nitrates. Certain medicines may be affected by Tadalamed or may affect how well Tadalamed works. Tell the doctor or pharmacist if you are already taking:

- alpha blockers (used to treat high blood pressure or urinary symptoms associated with benign prostatic hyperplasia).
- other medicines to treat high blood pressure.
- riociguat.
- medicines from the 5-alpha reductase inhibitor family (used to treat benign prostatic hyperplasia).
- medicines such as ketoconazole tablets (to treat fungal infections) and conazole inhibitors (to treat the AIDS virus or HIV infection).
- phenobarbital, phenytoin and carbamazepine (medicines to treat epilepsy).
- rifampicin, erythromycin, clarithromycin or itraconazole.
- other preparations for the treatment of erectile dysfunction.

Use of the medicine with food and drink: Tadalamed tablets are intended for oral use by men only. Swallow the tablet whole with a little water. The tablets can be taken with or without food.

Grapefruit juice may affect the way Tadalamed works and should be consumed with caution. Speak to the doctor for additional information.

Use of the medicine and alcohol consumption Drinking alcohol may affect your ability to obtain an erection and may temporarily lower your blood pressure.

If you took or plan to take Tadalamed, avoid excessive alcohol drinking (blood alcohol level of 0.08% or more), since this can also increase the risk of dizziness when standing up from a lying position.

Fertility

Tests performed in dogs found reduced sperm production. A reduction in sperm production was also seen in several men. These effects are unlikely to lead to impaired fertility.

Driving and operating machinery

Some men who took Tadalamed in clinical trials reported dizziness. Before driving or operating machinery, thoroughly assess how you react to the tablets.

Important information about some of the ingredients in this medicine

- Tadalamed contains lactose monohydrate. If you have been told by your doctor that you suffer from sensitivity to certain sugars, consult with your doctor before using the medicine.

- This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say, it is considered 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 dosage and treatment regimen of the preparation.

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

The recommended dosage for the treatment of erectile dysfunction in men, unless instructed otherwise by a doctor:

Tadalamed 10 mg – The recommended starting dosage is one 10 mg tablet before sexual contact. If the effect of this dosage is too weak, your doctor may increase the dosage to 20 mg.

Tadalamed 20 mg – The recommended starting dosage is one 10 mg tablet before sexual contact. Nevertheless, the doctor prescribed for you a dosage of one 20 mg tablet since he decided that the recommended 10 mg dosage is too weak for you. Take one Tadalamed tablet at least 30 minutes before sexual contact.

The effect of Tadalamed can last for up to 36 hours after taking the tablet.

Do not take Tadalamed more than once a day. It can be taken at any time of the day. Since the effect of Tadalamed is maintained for more than one day, avoid daily use of the preparation.

Tadalamed 2.5 and 5 mg – The recommended dosage is one 5 mg tablet taken once a day at approximately the same time of the day. The doctor may adjust the dosage to 2.5 mg, based on your response to Tadalamed. Do not take Tadalamed more than once a day.

Taking Tadalamed **"Daily"** enables reaching an erection during sexual stimulation at any time you choose during the 24 hours of the day.

Do not exceed the recommended dosage. It is important to note that when taken to treat erectile dysfunction, Tadalamed does not work without sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

The recommended dosage for treatment of benign prostatic hyperplasia symptoms, unless instructed otherwise by the doctor:

One Tadalamed 5 mg tablet per day. Take the tablet at around the same time every day.

The recommended dosage for treatment of men with erectile dysfunction and benign prostatic hyperplasia symptoms, unless instructed otherwise by the doctor:

One Tadalamed 5 mg tablet per day. Take the tablet at around the same time every day. Do not take Tadalamed more than once a day.

Crushing/halving/chewing: There is no information regarding crushing/halving/chewing the tablet. Take the tablet whole.

In addition, there is no information about use of the preparation in a feeding tube. Use this medicine at set time intervals, as determined by the attending doctor.

If you accidentally take a higher dosage If you accidentally took a higher dosage, refer to your doctor. You may experience side effects as listed in section 4.

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 forget to take the medicine If you forgot to take this medicine at the required time, take the medicine as soon as you remember, but do not take a double dose to compensate for a forgotten dose. Do not take Tadalamed more than once a day. Adhere to the treatment regimen recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a 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 this medicine 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. These side effects are generally mild to moderate.

Stop the treatment and refer to a doctor immediately if you suffer from:

- An allergic reaction, including skin rash (occurs infrequently).
- Chest pains – do not use nitrates and seek medical treatment immediately (occurs infrequently).
- Prolonged and potentially painful erection after taking Tadalamed (occurs rarely). If you have an erection like this, that lasts continuously for more than 4 hours, refer to a doctor immediately.
- Sudden loss of vision (occurs rarely).

Additional side effects that have been reported:

Common side effects – effects that occur in 1-10 in 100 users:

- Headache, back pain, muscle aches, pains in the hands and legs, facial flushing, nasal congestion and indigestion.

Uncommon side effects – effects that occur in 1-10 in 1,000 users:

- Dizziness, stomachache, vomiting, nausea, heartburn, blurred vision, eye pain, difficulty breathing, blood in the urine, prolonged erection, sensation of a pounding heart, rapid heart rate, high blood pressure, low blood pressure, nosebleeds, ringing or buzzing in the ear (tinnitus), edema in the hands, legs or ankles and sense of tiredness.

Rare side effects – effects that occur in 1-10 in 10,000 users:

- Fainting, epilepsy attack and passing memory loss, swelling of the eyelids, redness in the eyes, a sudden decrease or loss of hearing, hives (itchy red welts on the skin), penile bleeding, blood in the semen and increased sweating.

Rare cases of heart attack and stroke have been reported in men taking Tadalamed. Most of these men had pre-existing heart problems before taking the medicine.

There have been rare reports of partial, temporary or permanent decrease in vision or vision loss in one or both eyes.

Several rare side effects were reported among men who took Tadalamed, which did not occur in clinical trials. These included:

- Migraine, facial edema, severe allergic reaction, that manifests in swelling of the face or throat, severe rash, disorders in blood flow to the eyes, irregular heart rate, angina pectoris and sudden cardiac death.

Dizziness occurred more frequently in men over the age of 75 who took Tadalamed. Diarrhea occurred more frequently in men over the age of 65 who took Tadalamed.

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.

Reporting side effects

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) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

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 and blister. The expiry date refers to the last day of that month.

- Store at a temperature below 25°C.
- Do not dispose of the medicine in wastewater or the household waste. Consult the doctor or pharmacist as to how to dispose of the medicine. This will help protect the environment.

6. FURTHER INFORMATION

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

Lactose monohydrate, microcrystalline cellulose, low substituted hydroxypropyl cellulose, hydroxypropyl cellulose, magnesium stearate, sodium lauryl sulphate.

Instacoat Aqua III A03G30218: HPMC 2910/hypromellose, lactose monohydrate, triacetin, talc, titanium dioxide, yellow iron oxide.

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

Tadalamed 2.5 mg is a yellow, almond-shaped tablet, debossed with 'TAD' on one side and plain on the other side.

Tadalamed 5 mg is a yellow, almond-shaped tablet, debossed with 'T5' on one side and plain on the other side.

Tadalamed 10 mg is a yellow, almond-shaped tablet, debossed with 'T10' on one side and plain on the other side.

Tadalamed 20 mg is a yellow, almond-shaped tablet, debossed with 'T20' on one side and plain on the other side.

Package sizes:

Tadalamed 2.5 mg, Tadalamed 5 mg: A carton packaged 28 tablets in trays/blisters. The number of tablets in the package is indicated on the carton.

Tadalamed 10 mg: A carton package containing 4 tablets packaged in trays/blisters. The number of tablets in the package is indicated on the carton.

Tadalamed 20 mg: A carton package containing 4, 8 tablets packaged in trays/blisters. The number of tablets in the package is indicated on the carton.

Not all package sizes may be marketed.

Registration holder and importer: Inovamed Pharma Ltd., P.O. Box 2349, Bnei Brak 5112202.

Manufacturer: Umedica Laboratories Pvt. Ltd., Mumbai, India.

Revised in April 2022 in accordance with the Ministry of Health guidelines.

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

Tadalamed 2.5 mg: 169-53-37028

Tadalamed 5 mg: 169-54-37029

Tadalamed 10 mg: 169-52-37026

Tadalamed 20 mg: 169-55-37030