

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

The medicine is dispensed with a doctor's prescription only

TADAM

Film-coated tablets

The active ingredient and its quantity:

Tadam 5: each tablet contains Tadalafil 5 mg, for **"Daily"** use

Tadam 10: each tablet contains Tadalafil 10 mg, to be used **"As needed"**

Tadam 20: each tablet contains Tadalafil 20 mg, to be used **"As needed"**

For the list of the inactive and allergenic ingredients in the preparation, see in 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 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?

Tadam is intended for the treatment of erectile dysfunction in men, to obtain and maintain an erection.

Tadam belongs to a group of preparations called phosphodiesterase type 5 enzyme (PDE5) inhibitors.

Tadam "Daily" at a dosage of 5 mg is also intended for:

Treatment of benign prostatic hyperplasia symptoms.

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

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

Following sexual stimulation, **Tadam** works by relaxing the blood vessels in your penis, thereby allowing the flow of blood into it. The result of this is improved erectile function.

Tadam will not help you if you do not have erectile dysfunction.

It is important to note that **Tadam** 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 starting the stream of urine, a feeling of not completely emptying the bladder and a more frequent need to urinate, even at night. **Tadam** improves blood flow to, and relaxes the muscles of, the prostate and bladder, which may reduce the symptoms of benign prostatic hyperplasia. **Tadam** has been shown to improve these 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 "Further information").
- are taking a certain type of organic nitrate or a type that releases nitric oxide such as amyl nitrite. This is a group of medicines ("nitrates") used in the treatment of angina pectoris ("chest pain"). Tadalafil has been shown to increase the effect of these preparations. If you are taking any form of nitrate or are unsure, tell the doctor.
- have a serious heart disease or had a heart attack within the last 90 days.
- recently had a stroke that occurred in the last six months.
- have low blood pressure or uncontrolled high blood pressure.
- ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a medical condition called "stroke of the eye".
- are taking 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). PDE5 inhibitors, such as **Tadam**, have been shown to increase the hypotensive effect of this medicine. If you are taking riociguat or are unsure, tell the 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 the doctor before taking **Tadam**.

Be aware that sexual activity carries a possible risk to patients with heart disease because it puts an extra strain on the heart. If you have a heart problem, consult the doctor.

Since benign prostatic hyperplasia and prostate cancer may have identical symptoms, the doctor will check you for prostate cancer before prescribing you treatment with **Tadam** for benign prostatic hyperplasia. **Tadam** is not intended for the treatment of prostate cancer.

Before beginning treatment, tell the 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 **Tadam** is effective in patients who have had:

- Pelvic surgery.
- Removal of all or part of the prostate gland in which nerves of the gland are cut.

If you experience a sudden decrease/loss of vision or your vision is distorted or dimmed while you are taking **Tadam**, stop taking **Tadam** and refer to the doctor immediately.

Decreased or sudden hearing loss has been noted in some patients who took tadalafil. Although it is not known if this effect is directly related to tadalafil, if you experience decreased or sudden hearing loss, stop taking **Tadam** and refer to the 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.

Do not take **Tadam** if you are taking nitrates (see in section 2 "Do not use the medicine if you").

Some medicines may be affected by **Tadam** or they may affect how well **Tadam** 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.
- 5-alpha reductase inhibitors (used to treat benign prostatic hyperplasia).
- Medicines such as ketoconazole tablets (to treat fungal infections) and protease inhibitors (for treatment of the AIDS virus or HIV infection).
- Phenobarbital, phenytoin and carbamazepine (to treat epilepsy).
- Rifampicin, erythromycin, clarithromycin or itraconazole.
- Other preparations for erectile dysfunction.

Use of the medicine and food

Tadam 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 **Tadam** works and therefore, must be consumed with caution.

Speak to the doctor for more 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 **Tadam**, avoid excessive alcohol drinking (blood alcohol level of 0.08% or more), since this may 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 some men. These effects are unlikely to lead to impaired fertility.

Driving and operating machinery

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

Important information about some of the ingredients of the medicine

Tadam contains lactose

If you have been told by your doctor that you have an intolerance to certain sugars, consult your doctor before using the medicine. See section 6 "Further information".

Tadam contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, such that 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 usual dosage for the treatment of erectile dysfunction in men, unless instructed otherwise by a doctor:

Tadam 10 – the usual starting dosage is one 10 mg tablet before sexual activity. If the effect of this dosage is too weak, the doctor may increase the dosage to 20 mg.

Tadam 20 – the usual starting dosage is one 10 mg tablet before sexual activity. Nevertheless, the doctor gave you a dosage of one 20 mg tablet since he decided that the recommended dosage of 10 mg is too weak for you.

Take one **Tadam** tablet at least 30 minutes before sexual activity.

The effect of **Tadam** can persist for up to 36 hours after taking the tablet.

Do not take **Tadam** more than once a day.

Tadam 10 and 20 mg are intended for use prior to anticipated sexual activity and are not recommended for continuous daily use.

Tadam 5 – The usual dosage is one **Tadam 5** tablet taken once a day at approximately the same time of the day.

Do not take **Tadam** more than once a day.

Taking **Tadam 5** enables achievement of erection during sexual stimulation at any time you choose over 24 hours. Taking **Tadam 5** may be useful for men who anticipate having sexual activity two or more times per week.

It is important to emphasize that when taken to treat erectile dysfunction, **Tadam** 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 usual dosage for treatment of benign prostatic hyperplasia symptoms, unless instructed otherwise by the doctor:

One **Tadam 5** tablet once a day at approximately the same time of the day.

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

One **Tadam 5** tablet once a day at approximately the same time of the day.

Do not take **Tadam** more than once a day.

Do not exceed the recommended dose.

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

Use this medicine at set intervals as determined by the attending doctor.

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

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 the medicine as soon as you remember, but do not take a double dose to compensate for a forgotten dose. Do not take **Tadam** more than once a day.

Adhere to the treatment regimen as recommended by the doctor.

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 **Tadam** 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. These side effects are generally mild to moderate.

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

- Allergic reaction including skin rash (uncommon frequency).
- Chest pains – do not use nitrates and seek medical treatment immediately (uncommon frequency).
- Prolonged and possibly painful erection (priapism) after taking **Tadam** (rare frequency). If you have such an erection, which lasts continuously for than 4 hours, refer to a doctor immediately.
- Sudden loss of vision (rare frequency), distorted, dimmed, blurred central vision or sudden decrease of vision (frequency unknown).

Other side effects 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, nausea, vomiting, heartburn, blurred vision, eye pain, difficulty breathing, presence of blood in the urine, prolonged erection, sensation of pounding heartbeat, 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 of the eyes, a sudden decrease or loss of hearing, hives (itchy red bruises on the skin), penile bleeding, presence of blood in semen and increased sweating.

Rare cases of myocardial infarction and stroke have also been reported in men who were taking tadalafil – most of these men had heart problems before taking the medicine.

Partial, temporary or permanent decrease or loss of vision in one or both eyes has been rarely reported.

Rare side effects were reported among men who took tadalafil, 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 skin rash, disorders in blood flow to the eyes, irregular heart rate, angina pectoris and sudden cardiac death.
- Distorted, dimmed, blurred central vision or sudden decrease of vision (frequency unknown). Dizziness occurred more frequently among men over the age of 75 who took tadalafil. Diarrhea occurred more frequently among men over the age of 65 who took tadalafil.

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>

Additionally, you can report 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 below 25°C.
- Do not dispose of the medicine in wastewater or the household waste bin. Consult the doctor or pharmacist as to how to dispose of the medicine. These measures will help protect the environment.

6. FURTHER INFORMATION

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

Mannitol, Lactose anhydrous, Sodium lauryl sulphate, Croscarmellose sodium, Hydroxypropyl cellulose, Sodium stearyl fumarate, Magnesium stearate, Coating blend blue (HPMC, Titanium dioxide, Polyethylene glycol 400, FD&C blue No. 1 aluminum lake), Coating blend pearlescent purple (Polyvinyl alcohol, Talc, Polyethylene glycol 4000, MICA-based pearlescent pigment, Polysorbate 80).

Each **Tadam 5** tablet contains 24 mg lactose.

Each **Tadam 10** tablet contains 48 mg lactose.

Each **Tadam 20** tablet contains 96 mg lactose.

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

Tadam is packaged in trays (blisters), which are inserted into a carton package.

Tadam 5 are oval, biconvex, pearlescent, pale blue, film-coated tablets.

In each package there are 2, 4, 6, 8, 10, 14, 15, 20, 28 or 30 tablets.

Tadam 10 are round, biconvex, pearlescent, pale blue, film-coated tablets.

In each package there are 2, 4, 6 or 8 tablets.

Tadam 20 are oval, biconvex, pearlescent, pale blue, film-coated tablets.

In each package there are 2, 4, 6 or 8 tablets.

Not all package sizes may be marketed.

Registration holder and address: Unipharm Ltd., P.O. Box 16545, Tel Aviv, 6116401.

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

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

Tadam 5: 157 79 34602 01

Tadam 10: 157 81 34538 01

Tadam 20: 157 80 34537 01

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