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

The medicine is dispensed with a doctor's prescription only

Tadair

Tablets

Composition:

Each **Tadair** tablet contains:

Tadalafil 20 mg

For a list of the inactive ingredients, please 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 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 preparation is not intended for the treatment of children and adolescents under the age of 18.

Important information regarding Tadair:

- **Tadair** may cause a sudden drop in blood pressure when taken with nitrates. Consult with the doctor or pharmacist if you are unsure whether your prescribed medicines have nitrates in them.
- A person who is taking **Tadair** and requires urgent medical care because of heart problems, must inform the medical team that he is taking this medicine in order to avoid a situation in which he will be treated with nitrates!

1. WHAT IS THE MEDICINE INTENDED FOR?

Tadair is intended for the treatment of pulmonary hypertension in adults.

Therapeutic group:

Tadair belongs to a group of preparations called phosphodiesterase type 5 (PDE5) inhibitors. These medicines work by relaxing the blood vessels in the lungs, thus improving the flow of blood in the lungs. This results in an improved ability to do physical activity.

2. BEFORE USING THE MEDICINE

Do not use the preparation if:

- You are sensitive to tadalafil or any of the inactive ingredients contained in the medicine (see section 6: "Further information").
- You are taking nitrate preparations such as amyl nitrite for the treatment of chest pain.
- **Tadair** may increase the effect of these medicines. If you are taking any nitrate-containing preparation or are unsure, consult the doctor.
- You suffer or have suffered in the past from loss of vision as a result of a condition called NAION - non-arteritic anterior ischemic optic neuropathy (a condition described as "stroke of the eye").
- You had a heart attack in the last three months.
- You suffer from low blood pressure.
- You are being treated with riociguat, which is used to treat pulmonary arterial hypertension (high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (high blood pressure in the lungs as a result of blood clots). PDE5 inhibitors such as **Tadair** have been shown to increase the hypotensive effects of this medicine. If you are being treated with riociguat or are unsure, consult your doctor.

Special warnings regarding use of the medicine

Before starting treatment with Tadair, tell the doctor if:

- You are suffering from impaired function of the heart in addition to pulmonary hypertension.
- You are suffering from blood pressure problems.
- You are suffering from a hereditary eye disease.
- You are suffering from an abnormality of red blood cells called sickle cell anemia.
- You are suffering from cancer of the bone marrow called multiple myeloma.
- You are suffering from cancer of the blood cells called leukemia.
- There exists a deformation of your penis or you are suffering from situations that can cause an unwanted and persistent erection lasting more than 4 hours.
- You are suffering from a severe liver disease.
- You are suffering from a severe kidney disease.

If you experience a sudden decrease or loss of vision during the course of treatment with the medicine, contact the doctor immediately!

Children and Adolescents

The preparation is not intended for the treatment of children and adolescents under the age of 18.

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

- Bosentan (another treatment for pulmonary arterial hypertension).
- Nitrates (to treat angina pectoris).
- Alpha blockers used to treat hypertension or prostate problems.
- Riociguat.
- Rifampicin (to treat bacterial infections).
- Ketoconazole (to treat fungal infections).
- Ritonavir (for HIV treatment).
- PDE5 inhibitors for treating erectile dysfunction.

Use of the medicine and food

The medicine can be taken without regard to food.

Use of the medicine and alcohol consumption

Drinking alcohol may temporarily lower your blood pressure. During treatment with the medicine, avoid excessive drinking since this may lead to dizziness when moving from a sitting to standing position.

Pregnancy, breastfeeding and fertility

If you are pregnant, breastfeeding, think you might be pregnant or plan to become pregnant, consult the doctor before taking the medicine. Do not take **Tadair** when pregnant unless it is clinically necessary and the matter has been discussed with the attending doctor.

Do not breastfeed during treatment with **Tadair** since it is not known if the medicine passes into breast milk.

In dogs who were treated with this medicine, a decrease in sperm production was observed. Likewise, decreased sperm was observed in some of the patients. These effects are unlikely to lead to a lack of fertility.

Driving and using machines

Use of this medicine may cause dizziness. Check how you react to the preparation before driving or using dangerous machinery.

Important information regarding some of the ingredients of the medicine

This medicine contains lactose (see section 6: "Further Information"). If you know you have an intolerance to some sugars, consult the doctor before taking this medicine.

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.

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

Tadair contains 20 mg of tadalafil.

The usual dosage is generally two tablets of 20 mg once a day.

Take both tablets at the same time, one after the other.

If you suffer from a mild to moderate liver or kidney disease, the doctor may decide to reduce the dosage to one tablet a day.

Do not exceed the recommended dose.

Do not chew! Swallow the tablet with water.

The medicine can be taken without regard for food.

If necessary, the tablet can be crushed for immediate use. Do not halve the tablet.

If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to the doctor or proceed to a hospital emergency room and bring the package of the medicine with you. You may suffer from the side effects detailed in section 4.

If you forget to take this medicine at the required time, and not more than 8 hours have passed from the time you were supposed to take the medicine, take a dose as soon as you remember. Never take a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by the doctor.

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

4. SIDE EFFECTS

As with any medicine, use of **Tadair** 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.

If you experience any of the following side effects stop using the medicine and refer immediately to a doctor or a hospital:

- Allergic reaction including skin rashes (occurs frequently).
- Chest pain - do not use nitrates, but seek immediate medical assistance.
- Prolonged and possibly painful erection after taking **Tadair** (occurs infrequently). If you have such an erection which lasts continuously for more than 4 hours, contact a doctor immediately.
- Sudden loss of vision (occurs rarely).

Additional side effects:

Occur very frequently (occur in more than 1 in 10 patients): headache, flushing, nasal and sinus congestion (blocked nose), nausea, gastrointestinal disturbances (including abdominal pain and discomfort), muscle pain, back pain and pain in the extremities (including limb discomfort).

Occur frequently (occur in up to 1 in 10 patients): blurred vision, low blood pressure, nosebleed, vomiting, increased or abnormal uterine bleeding, swelling of the face, acid reflux, migraine, irregular heartbeat and fainting.

Occur infrequently (occur in up to 1 in 100 patients): seizures, passing memory loss, hives, excessive sweating, penile bleeding, presence of blood in semen and/or urine, high blood pressure, fast heart rate, sudden cardiac death and ringing in the ears.

PDE5 inhibitors are also used for the treatment of erectile dysfunction in men. The following side effects have been reported as occurring rarely:

Partial, temporary or permanent decrease or loss of vision in one or both eyes; serious allergic reaction which causes swelling of the face and throat; sudden decrease or loss of hearing.

Some side effects have been reported in men taking tadalafil for the treatment of erectile dysfunction. These effects were not reported in clinical studies for pulmonary hypertension and therefore, their frequency is unknown: swelling of the eyelids, eye pain, red eyes, heart attack and stroke.

Most but not all of those patients reporting fast heart rate or irregular heartbeat, heart attack, stroke or sudden cardiac death have suffered from a heart disease before being treated with tadalafil. It is not possible to determine whether these events were related directly to tadalafil treatment.

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) that directs you to the online form for reporting side effects. In addition, you can report to "Unipharm Ltd.".

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 a doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store below 25°C.

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, HPMC, Titanium dioxide, Polyethylene glycol, FD&C blue N. 1 aluminium lake, Polyvinyl alcohol, Talc, MICA-based pearlescent pigment, Polysorbate 80

Each **Tadair** tablet contains 96 mg lactose.

What the medicine looks like and contents of the package:

Tadair are light blue, coated oval biconvex tablets.

Registration holder and address: 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 January 2017

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 157-90-35176-00

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