

# REDEX®

Tadalafil

Film coated tablets 5, 10 and 20 mg

## Presentation:

**REDEX® 20:** Each Film coated tablet contains: 20 mg Tadalafil in packs of 2, 4 & 5 tablets.

**REDEX® 10:** Each Film coated tablet contains: 10 mg Tadalafil in packs of 2, 4 & 5 tablets.

**REDEX® 5:** Each Film coated tablet contains: 5 mg Tadalafil in packs of 30 tablets.

**Excipients:** Lactose Monohydrate, Croscarmellose Sodium, Microcrystalline Cellulose, Sodium Lauryl sulfate, Povidone K30, Magnesium Stearate, Yellow Iron Oxide & Opadry II white.

## Pharmaceutical form:

Film coated tablets for oral use.

## Pharmacotherapeutic group:

Drugs used in erectile dysfunction, **ATC code:** G04BE08

## Therapeutic Indications:

**erectile dysfunction:** This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. **REDEX®** has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity. Following sexual stimulation **REDEX®** works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. The result of this is improved erectile function.

**REDEX®** will not help you if you do not have erectile dysfunction.

It is important to note that **REDEX®** for the treatment of erectile dysfunction 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.

**REDEX® 5 mg only:** Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males: urinary symptoms associated with a common condition called benign prostatic hyperplasia. This is when the prostate gland gets bigger with age. Symptoms include difficulty in starting to pass water, a feeling of not completely emptying the bladder and a more frequent need to pass water even at night. **REDEX®** improves blood flow to, and relaxes the muscles of, the prostate and bladder which may reduce symptoms of benign prostatic hyperplasia. **REDEX®** has been shown to improve these urinary symptoms as early as 1-2 weeks after starting treatment.

## Posology and method of administration:

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. **REDEX®** tablets are for oral use in men only. Swallow the tablet whole with some water. The tablets can be taken with or without food.

For the treatment of erectile dysfunction

**REDEX® 10, 20:** one 10 mg tablet before sexual activity. If the effect of this dose is too weak your doctor may increase the dose to 20 mg. **REDEX®** tablets are for oral use. You may take a **REDEX® 10, 20** tablet at least 30 minutes before sexual activity. **REDEX® 10, 20** may still be effective up to 36 hours after taking the tablet.

Do not take **REDEX®** more than once a day. **REDEX® 10** mg and

**REDEX® 20** mg is intended for use prior to anticipated sexual activity and is not recommended for continuous daily use.

**REDEX® 5:** one 5 mg tablet taken once a day at approximately the same time of the day.

Do not take **REDEX® 5** more than once a day.

When taken once a day **REDEX® 5** allows you to obtain an erection, when sexually stimulated, at any time point during the 24 hours of the day. Once a day dosing of **REDEX® 5** may be useful to men who anticipate having sexual activity two or more times per week.

It is important to note that **REDEX®** 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.

## For the treatment benign prostatic hyperplasia

### Only REDEX® 5:

The dose is one 5 mg tablet taken once a day at approximately the same time of the day. If you have benign prostatic hyperplasia and erectile dysfunction, the dose remains one 5 mg tablet taken once a day. Do not take **REDEX® 5** more than once a day.

If you forget to take **REDEX® 5** Take your dose as soon as you remember but do not take a double dose to make up for a forgotten tablet. You should not take **REDEX® 5** more than once a day.

## Contra-indications:

Do not take **REDEX®** if you:

- are allergic to tadalafil or any of the other ingredients of this medicine
- are taking any form of organic nitrate or nitric oxide donors 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 effects of these medicines. If you are taking any form of nitrate or are unsure tell your doctor.
- have serious heart disease or recently had a heart attack within the last 90 days.

- recently had a stroke within the last 6 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 condition described as "stroke of the eye".

- are taking guanylate cyclase stimulators, such as riociguat, with PDE5 inhibitors, including tadalafil. The co-administration is contraindicated as it may potentially lead to symptomatic hypotension. Riociguat, this drug is 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 tadalafil, have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

## Warnings and Precautions for use:

Talk to your doctor before taking **REDEX®**.

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

### Only with REDEX® 5

Since benign prostatic hyperplasia and prostate cancer may have the same symptoms, your doctor will check you for prostate cancer before starting treatment with tadalafil for benign prostatic hyperplasia. Tadalafil does not treat prostate cancer.

Before taking the tablets, tell your doctor if you have:

- sickle cell anaemia (an abnormality of red blood cells).
- multiple myeloma (cancer of the bone marrow).
- leukaemia (cancer of the blood cells).
- any deformation of your penis.
- a serious liver problem.
- a severe kidney problem.

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

- pelvic surgery.
- removal of all or part of the prostate gland in which nerves of the prostate are cut (radical nonnerve-sparing prostatectomy).

If you experience sudden decrease or loss of vision, stop taking **REDEX®** and contact your doctor immediately.

**REDEX®** is not intended for use by women or by children and adolescents under the age of 18.

## Fertility:

When dogs were treated there was reduced sperm development in the testes. A reduction in sperm was seen in some men. These effects are unlikely to lead to a lack of fertility.

## Driving and using machines:

Some men taking tadalafil in clinical studies have reported dizziness. Check carefully how you react to the tablets before driving or using machines.

**REDEX®** contains lactose: If you have an intolerance to some sugars, contact your doctor before taking this medicine.

## Use During pregnancy and lactation:

Tadalafil is not intended for use by women.

## Drug Interactions:

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Do not take **REDEX®** if you are already taking nitrates. Some medicines may be affected by **REDEX®** or they may affect how well **REDEX®** will work. Tell your doctor or pharmacist if you are already taking:

- an alpha blocker (used to treat high blood pressure or urinary symptoms associated with benign prostatic hyperplasia).
- other medicines to treat high blood pressure.
- riociguat.
- a 5- alpha reductase inhibitor (used to treat benign prostatic hyperplasia).
- medicines such as ketoconazole tablets (to treat fungal infections) and protease inhibitors for treatment of AIDS or HIV infection.
- phenobarbital, phenytoin and carbamazepine (anticonvulsant medicines).
- rifampicin, erythromycin, clarithromycin or itraconazole.
- other treatments for erectile dysfunction.

## Drink and alcohol:

Grapefruit juice may affect how well **REDEX®** will work and should be taken with caution. Talk to your doctor for further information. Drinking alcohol may temporarily lower your blood pressure. If you have taken or are planning to take **REDEX®**, avoid excessive drinking (blood alcohol level of 0.08% or greater), since this may increase the risk of dizziness when standing up.

## Undesirable effects:

Like all medicines, this medicine can cause side effects, although not everybody gets them. These effects are normally mild to moderate in nature.

If you experience any of the following side effects stop using the medicine and seek medical help immediately:

- allergic reactions including rashes (frequency uncommon).
- chest pain - do not use nitrates but seek immediate medical assistance (frequency uncommon).
- prolonged and possibly painful erection after taking tadalafil (frequency rare).
- If you have such an erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.
- sudden loss of vision (frequency rare).

Other side effects have been reported:

**Common (seen in 1 to 10 in every 100 patients)**

- headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion, indigestion and reflux.

**Uncommon (seen in 1 to 10 in every 1 000 patients)**

- dizziness, stomach ache, blurred vision, eye pain, increased sweating, difficulty in breathing, penile bleeding, presence of blood in semen and/or urine, pounding heartbeat sensation, a fast heart rate, high blood pressure, low blood pressure, nose bleeds and ringing in the ears.

**Rare (seen in 1 to 10 in every 10 000 patients)**

- fainting, seizures and passing memory loss, swelling of the eyelids, red eyes, sudden decrease or loss of hearing and hives (itchy red welts on the surface of the skin).

Heart attack and stroke have also been reported rarely in men taking tadalafil.

Most of these men had known heart problems before taking this medicine. Partial, temporary, or permanent decrease or loss of vision in one or both eyes has been rarely reported. Some additional rare side effects have been reported in men taking tadalafil that were not seen in clinical trials.

These include:

- migraine, swelling of the face, serious allergic reaction which causes swelling of the face or throat, serious skin rashes, some disorders affecting blood flow to the eyes, irregular heartbeats, angina and sudden cardiac death. The side effects dizziness and diarrhoea have been reported more frequently in men over 75 years of age taking tadalafil.

## Overdose:

If you take more **REDEX®** than you should; tell your doctor.

## Pharmacological Properties:

**REDEX®** belongs to a group of medicines called phosphodiesterase type 5 inhibitors. Following sexual stimulation; **REDEX®** works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. The result of this is improved erectile function.

## Special precautions for storage:

Store below 30°C.

### This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor
- Keep medicament out of the reach of children.

COUNCIL OF ARAB HEALTH MINISTERS  
UNION OF ARAB PHARMACISTS

Al-Taqaddom Pharmaceutical Industries  
Amman-Jordan

PHARMA  
Trade Society

Rev. Date: June 2019  
I- Redex-RDX-LM1-RO/AE

Dimensions: 15 x 24 cm

Pantone Black C