

**Package leaflet: Information for the users**

# Tadalafil 10 mg Film-Coated Tablets

**Read all this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your pharmacist or doctor has told you.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- If you get any side effects talk to your pharmacist or doctor. This includes any possible side effects not listed in this leaflet. See section 4
- If you have taken Tadalafil as directed (see section 3) and were not able to get or keep an erection hard enough for satisfactory sex, you should talk to your pharmacist or doctor.

**What is in this leaflet:**

1. What Tadalafil is and what it is used for
2. What you need to know before you take Tadalafil
3. How to take Tadalafil
4. Possible side effects
5. How to store Tadalafil
6. Contents of the pack and other information

## 1. What Tadalafil is and what it is used for

Tadalafil is a treatment for adult men with erectile dysfunction. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. Tadalafil has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.

Tadalafil contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Following sexual stimulation Tadalafil 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. Tadalafil will not help you if you do not have erectile dysfunction.

It is important to know that you will not get an erection just by taking Tadalafil tablets. This medicine works with your body's natural function to get an erection only when you are sexually stimulated. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

## 2. What you need to know before you take Tadalafil

**Do not take Tadalafil if you:**

- are allergic to tadalafil or any of the other ingredients of this medicine (listed in section 6)
- do not have an erection problem, as this medicine will not provide any benefit to you
- take any **medicines called nitrates or nitric oxide donors** (such as glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate for the relief of chest pain or heart failure, or nicorandil, molsidomine or sodium nitroprusside), as the combination may lead to a dangerous fall in blood pressure
- take amyl nitrite also known as "poppers" as recreational drugs, as the combination may lead to a dangerous fall in blood pressure
- have been advised by your doctor to avoid sexual activity because of a problem with your heart or blood vessels, such as recent heart attack (within the last 90 days) or stroke (within the last 6 months), unstable angina or severe cardiac failure
- have low blood pressure or uncontrolled high blood pressure
- have ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as "stroke of the eye"
- take riociguat or other medicines belonging to a group called guanylate cyclase stimulators. 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
- have a deformed penis (such as angulation, cavernosal fibrosis or Peyronie's disease)
- are a woman
- are under 18 years of age.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Tadalafil.

Sexual activity can put extra strain on your heart. If you have a heart problem or think you might have a heart problem you should tell your pharmacist or doctor.

It is important to have a check-up with your doctor as soon as possible within the first 6 months of using Tadalafil to ensure that your erection problems are not caused by another serious health condition. Even if you feel healthy, your erection problems may be linked to other serious health conditions. Erectile dysfunction may be an early sign of:

- heart and blood vessel problems
- diabetes
- high blood pressure
- depression

You should discuss your symptoms and these conditions with your doctor if you have not already done so.

**Cardiovascular risk factors**

Before taking Tadalafil, in order to ensure this medicine is suitable for you and that you are fit enough to have sex, tell your doctor if you:

- get very breathless or feel any pain in the chest with light or moderate activity (e.g. walking briskly for 20 minutes or climbing two flights of stairs). Your doctor may need to check whether your heart can take the additional strain of having sex
- have or have ever had any heart disease or heart surgery e.g. valvular heart disease (damaged or diseased heart valve), cardiomyopathy (disease of the heart muscle), arrhythmia (irregular heart beat)
- have high blood pressure that is not controlled
- have an abnormal or impaired left lower heart chamber
- have a restriction of the blood flow from the heart e.g. aortic stenosis,
- have Multiple System Atrophy (a rare condition causing severe loss of control of blood pressure due to a shrinkage of muscle or nerve tissue).

**Other risk factors**

Talk to your doctor before taking Tadalafil if you:

- have ever had an erection that lasted more than 4 hours (called priapism) or have any condition which can cause priapism which includes sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), or multiple myeloma (cancer of bone marrow)
- take any other medicines listed in this leaflet. Please refer to section 2 'Other medicines and Tadalafil'
- have any deformation of your penis
- have a serious liver problem
- have a severe kidney problem.

Speak to your doctor if you have:

- undergone pelvic surgery or removal of all or part of the prostate gland in which nerves of the prostate are cut (radical non-nerve-sparing prostatectomy) as it is not known if Tadalafil will be effective for you
- known hereditary degenerative retinal disorders such as retinitis pigmentosa (a genetic disorder that causes loss of vision) as it is unknown whether Tadalafil is safe for you to use.

If you experience sudden decrease or loss of vision or your vision is distorted, dimmed while you are taking tadalafil, stop taking Tadalafil and contact your doctor immediately.

Decreased or sudden hearing loss has been noted in some patients taking Tadalafil. Although it is not known if the event is directly related to Tadalafil, if you experience decreased or sudden hearing loss, stop taking Tadalafil and contact your doctor immediately.

**Children and adolescents**

Tadalafil is not intended for use by children and adolescents under the age of 18.

**Other medicines and Tadalafil**

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

**Do not take Tadalafil if you take:**

- **NITRATE medicines (such as glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate) or nitric oxide donors (such as amyl nitrite ("poppers"), nicorandil, molsidomine or sodium nitroprusside).** These are often used for the relief of chest pain (angina pectoris), or heart failure. Using Tadalafil with any of these medicines may lead to a dangerous fall in blood pressure.
- Riociguat (or other medicines of a group called guanylate cyclase stimulators), 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 due to blood clots).

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**Perrigo®**

| Job Information |                                                      | Version Information |               | Colours   |         |
|-----------------|------------------------------------------------------|---------------------|---------------|-----------|---------|
| Product Name:   | Perrigo Tadalafil 10mg Film-Coated Tablets           | Version:            | Operator:     | Process   | Pantone |
| Project Name:   | NPD for Storebrand and Perrigo Tadalafil 10g 4ct_8ct | 5                   | DH            | Black     | N/A     |
| Program No.:    | 001355                                               | Date:               | 21 / JUL / 25 | N/A       | N/A     |
| Component No.:  | DYW00000J1                                           |                     |               | N/A       | N/A     |
| Licence No.:    | PL 16028/0193                                        |                     |               | N/A       | N/A     |
| Supplier:       | Medreich                                             |                     |               | N/A       | N/A     |
| Cutter Ref.:    | L6025                                                |                     |               | N/A       | N/A     |
| Dimensions:     | 120 x 420mm                                          |                     |               | Technical | Cutter  |
|                 |                                                      |                     |               |           | Guides  |
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