

PACKAGE LEAFLET

Package leaflet: Information for the patient

Tadalafil Mylan 20 mg film-coated tablets

Tadalafil

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

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

Tadalafil Mylan 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 Mylan contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors. Following sexual stimulation Tadalafil Mylan 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 Mylan will not help you if you do not have erectile dysfunction.

It is important to note that tadalafil 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.

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

Do not take Tadalafil Mylan:

- if you are allergic to tadalafil or any of the other ingredients of this medicine (listed in section 6).
- if you 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.
- if you have serious heart disease or recently had a heart attack within the last 90 days.
- if you had a stroke within the last 6 months.
- if you have low blood pressure or uncontrolled high blood pressure.
- if you ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as “stroke of the eye”.
- if you are taking 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 Mylan, 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

Talk to your doctor before taking Tadalafil Mylan.

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.

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 non nerve-sparing prostatectomy).

If you experience sudden decrease or loss of vision, stop taking Tadalafil Mylan 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 Mylan and contact your doctor immediately.

Tadalafil Mylan is not intended for use by women.

Children and adolescents

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

Other medicines and Tadalafil Mylan

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

Do not take Tadalafil Mylan if you are already taking nitrates.

Some medicines may be affected by Tadalafil Mylan or they may affect how well Tadalafil Mylan 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.

Tadalafil Mylan with drink and alcohol

Information on the effect of alcohol is in section 3. Grapefruit juice may affect how well Tadalafil Mylan will work and should be taken with caution. Talk to your doctor for further information.

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.

Tadalafil Mylan contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Tadalafil Mylan

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Tadalafil Mylan tablets are for oral use in men only. Swallow the tablet whole with some water. The tablets can be taken with or without food.

The recommended starting dose is one 10 mg tablet before sexual activity. However, you have been given the dose of one 20 mg tablet as your doctor has decided that the recommended dose of 10 mg is too weak.

You may take tadalafil at least 30 minutes before sexual activity.
Tadalafil may still be effective up to 36 hours after taking the tablet.

Do not take Tadalafil Mylan more than once a day. Tadalafil Mylan 10 mg and 20 mg is intended for use prior to anticipated sexual activity and is not recommended for continuous daily use.

It is important to note that Tadalafil Mylan 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.

Drinking alcohol may affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or are planning to take Tadalafil Mylan, avoid excessive drinking (blood alcohol level of 0.08% or greater), since this may increase the risk of dizziness when standing up.

If you take more Tadalafil Mylan than you should

Contact your doctor. You may experience side effects described in section 4.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side 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).
- priapism, a 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 (may affect up to 1 in 10 people)

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

Uncommon (may affect up to 1 in 100 people)

- dizziness, stomach ache, feeling sick, being sick (vomiting), reflux, blurred vision, eye pain, difficulty in breathing, presence of blood in urine, prolonged erection, pounding heartbeat sensation, a fast heart rate, high blood pressure, low blood pressure, nose bleeds, ringing in the ears, swelling of the hands, feet or ankles and feeling tired.

Rare (may affect up to 1 in 1,000 people)

- 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), penile bleeding, presence of blood in semen and increased sweating.

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 effect dizziness has been reported more frequently in men over 75 years of age taking tadalafil. Diarrhoea has been reported more frequently in men over 65 years of age taking tadalafil.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland:

HPRA Pharmacovigilance, Earlsfort Terrace,

IRL - Dublin 2; Tel: +353 16764971;

Fax: +353 16762517.

Website: www.hpra.ie; e-mail: medsafety@hpra.ie

United Kingdom:

Yellow Card Scheme Website:

www.mhra.gov.uk/yellowcard

5. How to store Tadalafil Mylan

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tadalafil Mylan contains

- The active substance is tadalafil. Each tablet contains 20 mg of tadalafil.
- The other ingredients are:
Tablet core: lactose anhydrous (see section 2 'Tadalafil Mylan contains lactose'), poloxamer 188, cellulose microcrystalline (pH101), povidone (K-25), croscarmellose sodium, magnesium stearate, sodium laurilsulfate, silica colloidal anhydrous.
Film-coat: lactose monohydrate, hypromellose (E464), titanium dioxide (E171), iron oxide yellow (E172), triacetin.

What Tadalafil Mylan looks like and contents of the pack

Tadalafil Mylan 20 mg is a light yellow, film-coated, round, biconvex tablet marked with 'M' on one side of the tablet and 'TL4' on the other side.

Tadalafil Mylan 20 mg is available in blister packs containing 2, 4, 8, 12 and 24 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Generics [UK] Limited,
Station Close, Potters Bar
Hertfordshire
EN6 1TL
United Kingdom

Manufacturer

McDermott Laboratories Ltd. t/a Gerard Laboratories
35/36 Baldoye Industrial Estate, Grange Road
Dublin 13
Ireland

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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United Kingdom

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This leaflet was last revised in 06/2017

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.