

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sildenafil Mylan 25 mg Film-Coated Tablets
Sildenafil Mylan 50 mg Film-Coated Tablets
Sildenafil Mylan 100 mg Film-Coated Tablets
sildenafil

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Sildenafil Mylan is and what it is used for
2. Before you take Sildenafil Mylan
3. How to take Sildenafil Mylan
4. Possible side effects
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1. WHAT SILDENAFIL MYLAN IS AND WHAT IT IS USED FOR

Sildenafil Mylan belongs to a group of medicines called phosphodiesterase type 5 (PDE 5) inhibitors. It works by helping to relax the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited. Sildenafil Mylan will only help you to get an erection if you are sexually stimulated. You should not take Sildenafil Mylan if you do not have erectile dysfunction.

You should not take Sildenafil Mylan if you are a woman.

Sildenafil Mylan is a treatment for men with erectile dysfunction, sometimes known as impotence. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

2. BEFORE YOU TAKE SILDENAFIL MYLAN

Do not take Sildenafil Mylan

- If you are taking medicines called nitrates, as the combination may cause a potentially dangerous decrease in your blood pressure. Tell your doctor if you are taking any of these medicines which are often given for relief of angina pectoris (or “chest pain”). If you are not certain, ask your doctor or pharmacist.
- If you are using any of the drugs known as nitric oxide donors such as amyl nitrite (“poppers”) as the combination may also lead to a potentially dangerous decrease in your blood pressure.
- If you are allergic (hypersensitive) to sildenafil or any of the other ingredients of Sildenafil Mylan If you have a severe heart or liver problem.
- If you have recently had a stroke or a heart attack, or if you have low blood pressure.
- If you have certain rare inherited eye diseases (such as retinitis pigmentosa).
- If you have ever had loss of vision because of non-arteritic anterior ischaemic optic neuropathy (NAION)

Take special care with Sildenafil Mylan

Tell your doctor

- if you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow)
- if you have a deformity of your penis or Peyronie's Disease.
- if you have problems with your heart. Your doctor should in that case carefully check whether your heart can take the additional strain of having sex.
- if you currently have a stomach ulcer, or a bleeding problem (such as haemophilia).
- if you experience sudden decrease or loss of vision, stop taking Sildenafil Mylan and contact your doctor immediately.

You should not use Sildenafil Mylan with any other oral or local treatments for erectile dysfunction.

Special considerations for children and adolescents

Sildenafil Mylan should not be given to individuals under the age of 18.

Special considerations for patients with kidney or liver problems

You should tell your doctor if you have kidney or liver problems. Your doctor may decide on a lower dose for you.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without prescription.

Sildenafil Mylan tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell any healthcare professional treating your condition that you have taken Sildenafil Mylan and when you did. Do not take Sildenafil Mylan with other medicines unless your doctor tells you that you can.

You should not take Sildenafil Mylan if you are taking medicines called nitrates as the combination of these products may cause a potentially dangerous decrease in your blood pressure. Always tell your doctor or pharmacist if you are taking any of these medicines that are often used for the relief of angina pectoris (or "chest pain").

You should not take Sildenafil Mylan if you are using any of the drugs known as nitric oxide donors such as amyl nitrite ("poppers") as the combination may also lead to a potentially dangerous decrease in your blood pressure.

If you are taking medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25 mg) of Sildenafil Mylan.

Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking sildenafil with alpha-blockers. This is most likely to occur within 4 hours after taking Sildenafil Mylan. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your alpha-blocker before you start Sildenafil Mylan. Your doctor may start you on a lower dose (25 mg) of Sildenafil Mylan.

Taking Sildenafil Mylan with food and drink

Sildenafil Mylan can be taken with or without food. However, you may find that Sildenafil Mylan takes longer to start working if you take it with a heavy meal.

Drinking alcohol can temporarily impair your ability to get an erection. To get the maximum benefit from your medicine, you are advised not to drink excessive amounts of alcohol before taking Sildenafil Mylan.

Pregnancy and breast-feeding

Sildenafil Mylan is not indicated for use by women

Driving and using machines

Sildenafil Mylan can cause dizziness and can affect vision. You should be aware of how you react to Sildenafil Mylan before you drive or use machinery.

3. HOW TO TAKE SILDENAFIL MYLAN

Always take Sildenafil Mylan exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual starting dose is 50 mg.

You should not take Sildenafil Mylan more than once a day.

You should take Sildenafil Mylan about one hour before you plan to have sex. Swallow the tablet whole with a glass of water.

If you have the impression that the effect of Sildenafil Mylan is too strong or too weak, talk to your doctor or pharmacist. Sildenafil Mylan will only help you to get an erection if you are sexually stimulated. The amount of time Sildenafil Mylan takes to work varies from person to person, but it normally takes between half an hour and one hour. You may find that Sildenafil Mylan takes longer to work if you take it with a heavy meal.

If Sildenafil Mylan does not help you to get an erection, or if your erection does not last long enough for you to complete sexual intercourse you should tell your doctor.

You should not use Sildenafil Mylan more than once a day.

If you take more Sildenafil Mylan than you should

You may experience an increase in side effects and their severity. Doses above 100 mg do not increase the efficacy.

You should not take more tablets than your doctor tells you to.

Contact your doctor if you take more tablets than you should. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sildenafil Mylan can cause side effects, although not everybody gets them. The side effects reported in association with the use of sildenafil are usually mild to moderate and of a short duration.

If you have chest pains during or after intercourse:

- Get in a semi-sitting position and try to relax
- Do not use nitrates to treat your chest pain
- Contact your doctor immediately

All medicines including Sildenafil Mylan can cause allergic reactions. You should contact your doctor immediately if you experience any of the following symptoms after taking Sildenafil Mylan:

- sudden wheeziness,
- difficulty in breathing or dizziness,
- swelling of the eyelids, face, lips or throat.

Prolonged and sometimes painful erections have been reported after taking Sildenafil Mylan. If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.

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

Very common side effects (likely to occur in more than 1 in 10 patients):

- headache

Common side effects (likely to occur in 1 to 10 patients in 100):

- facial flushing, indigestion, effects on vision (including colour tinge to vision, light sensitivity, blurred vision or reduced sharpness of vision) stuffy nose and dizziness.

Uncommon side effects (likely to occur in 1 to 10 patients in 1000)

- vomiting, skin rash, bleeding at the back of the eye, bloodshot eyes/red eyes, eye pain, double vision, abnormal sensation in the eye, irregular or rapid heartbeat, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, nausea, dry mouth, chest pain and feeling tired.

Rare side effects (likely to occur in 1 to 10 patients in 10000)

- high blood pressure, low blood pressure, fainting, stroke, nosebleed and sudden decrease or loss of hearing.

Additional side effects reported from post-marketing experience include: pounding heartbeat, chest pain, sudden death, heart attack or temporary decreased blood flow to parts of the brain. Most, but not all, of these men had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to sildenafil. Cases of convulsions or seizures and serious skin reactions characterised by rash, blisters, peeling skin and pain which require immediate medical attention have also been reported.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet please tell your doctor.

5. HOW TO STORE SILDENAFIL MYLAN

- Keep out of the reach and sight of children.
- This medicine does not require any special storage conditions.
- Do not use Sildenafil Mylan after the expiry date which is stated on the carton and blister foil. The expiry date refers to the last day of the month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Sildenafil Mylan contains

- The active substance is sildenafil. Each tablet contain 25 mg, 50 mg or 100 mg of sildenafil (as sildenafil citrate)
- The other ingredients are:
 - Tablet Core - Cellulose Microcrystalline, Calcium Hydrogen Phosphate Anhydrous, Croscarmellose Sodium, Magnesium Stearate
 - Film Coating - Hypromellose (E464), Titanium Dioxide (E171), Indigo Carmine Aluminium Lake (E132), Triacetin

What Sildenafil Mylan looks like and contents of the pack

The 25 mg tablets are blue film-coated, round biconvex tablets marked “M” on one side and “SL over 25” on the other side.

The 50 mg tablets are blue film-coated, round biconvex tablets marked “M” on one side and “SL over 50” on the other side.

The 100 mg tablets are blue film-coated, round biconvex tablets marked “M” on one side and “SL over 100” on the other side.

The tablets are provided in blister packs containing 1, 2, 4, 8 or 12 tablets. Some pack sizes may not be marketed.

Marketing Authorisation Holder:

McDermott Laboratories Ltd. T/A Gerard Laboratories
35-36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturers:

McDermott Laboratories Ltd. T/A Gerard Laboratories
35-36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft.
H-2900 Komárom, Mylan utca 1, Hungary.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Sildenafil Arcana 25 mg, 50 mg, 100 mg Filmtabletten
Belgium	NL: Sildenafil Mylan 25 mg, 50 mg, 100 mg filmomhulde tabletten FR: Sildenafil Mylan 25 mg, 50 mg, 100 mg comprimés pelliculés DE: Sildenafil Mylan 25 mg, 50 mg, 100 mg Filmtabletten
Bulgaria	Sildenafil Mylan 25 mg, 50 mg, 100 mg film-coated tablets
Czech Republic	Sildenafil Mylan 50 mg, 100 mg potahované tablety
Denmark	Sildenafil Mylan
Finland	Sildenafil Mylan 50 mg ja 100 mg kalvopäällysteiset tabletit
France	Sildenafil Mylan 25 mg, 50 mg, 100 mg comprimés pelliculés
Germany	duraviril 25 mg, 50 mg, 100 mg Filmtabletten
Greece	Sildenafil Mylan 25 mg, 50 mg, 100 mg film-coated tablets
Hungary	Sildenafil Mylan 25 mg, 50 mg, 100 mg filmtableta
Iceland	Sildenafil Mylan 25 mg, 50 mg, 100 mg Filmuhúðaðar töflur
Ireland	Sildenafil Mylan 25 mg, 50 mg, 100 mg film-coated tablets
Italy	Sildenafil Mylan 25 mg, 50 mg, 100 mg compresse rivestite con film
Norway	Sildenafil Mylan 50 mg, 100 mg tabletter, filmdrasjerte
Poland	Sildenafil Mylan, 25 mg, 50 mg, 100 mg, Tabletki powlekane
Portugal	Sildenafil Mylan 25 mg, 50 mg, 100 mg comprimido revestido por película
Romania	Sildenafil Mylan 25 mg, 50 mg, 100 mg comprimate filmate
Slovakia	Sildenafil Mylan 50 mg / 100 mg Filmom obalené tablety
Slovenia	Sildenafil Mylan 50 mg, 100 mg filmsko obložene tablete
Spain	Sildenafil Mylan 25 mg, 50 mg, 100 mg comprimidos recubiertos con película
Sweden	Sildenafil Mylan 25 mg, 50 mg, 100 mg filmdragerade tabletter
The Netherlands	Sildenafil Mylan 25 mg, 50 mg, 100 mg, filmomhulde tabletten
United Kingdom	Sildenafil Mylan 25 mg, 50 mg, 100 mg film-coated tablets

This leaflet was last approved in 09/2013.