

PACKAGE LEAFLET

Package leaflet: Information for the patient

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 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 Sildenafil Mylan is and what it is used for
2. What you need to know before you take Sildenafil Mylan
3. How to take Sildenafil Mylan
4. Possible side effects
5. How to store Sildenafil Mylan
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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.

Sildenafil Mylan is a treatment for adult 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. What you need to know before you take Sildenafil Mylan

Do not take Sildenafil Mylan

- if you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6)
- if you are taking medicines called nitrates, as the combination may lead to a dangerous fall 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 medicines known as nitric oxide donors such as amyl nitrite (“poppers”) as the combination may also lead to a dangerous fall in your blood pressure
- if you are taking riociguat. This medicine 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 sildenafil have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.
- 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 due to non-arteritic anterior ischaemic optic neuropathy (NAION).

Warnings and precautions

Talk to your doctor or pharmacist before taking Sildenafil Mylan:

- 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 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 treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitors.

You should not take Sildenafil Mylan if you do not have erectile dysfunction.

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

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.

Other medicines and Sildenafil Mylan

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

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 or nicorandil (a nitrate like medicine) as the combination of these products may lead to a dangerous fall 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 medicines known as nitric oxide donors such as amyl nitrite ("poppers") as the combination may also lead to a dangerous fall in your blood pressure.

Tell your doctor or pharmacist if you are already taking riociguat.

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 happen within 4 hours after taking Sildenafil Mylan. To reduce the chance that these symptoms might happen, 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.

Tell your doctor or pharmacist if you are taking, have recently taken or might take medicines containing sacubitril/valsartan, used to treat heart failure.

You should not use Sildenafil Mylan with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or bosentan.

Sildenafil Mylan with food, drink and alcohol

Sildenafil Mylan can be taken with or without food (see section 3 “How to take Sildenafil Mylan”). 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, breast-feeding and fertility

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.

Sildenafil Mylan contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Sildenafil Mylan

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

The recommended 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 feel 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.

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, this medicine 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 experience any of the following serious side effects stop taking Sildenafil Mylan and seek medical help immediately:

Uncommon (may affect up to 1 in 100 people):

- An allergic reaction
Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.
- Chest pains
If this occurs during or after intercourse, get in a semi-sitting position and try to relax.
Do not use nitrates to treat your chest pain.

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

- Prolonged and sometimes painful erections
If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.
- A sudden decrease or loss of vision.
- Serious skin reactions
Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever.
- Seizures or fits.

Other side effects reported:

Very common (may affect more than 1 in 10 people):

- headache.

Common (may affect up to 1 in 10 people):

- nausea (feeling sick), facial flushing, hot flush (symptoms include a sudden feeling of heat in your upper body), indigestion, effects on vision (including colour tinge to vision like blue vision, blurred vision, visual disturbance) stuffy nose and dizziness.

Uncommon (may affect up to 1 in 100 people):

- vomiting, skin rash, eye irritation, bloodshot eyes/red eyes, eye pain, seeing flashes of light, visual brightness, light sensitivity, watery eyes, pounding heartbeat, rapid heartbeat, high blood pressure, low blood pressure, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, dry mouth, blocked or stuffy sinuses, inflammation of the lining of the nose (symptoms include runny nose, sneezing and stuffy nose), upper abdominal pain, gastro-oesophageal reflux disease (symptoms include heartburn), pain in the arms or legs, nosebleed, presence of blood in urine, feeling hot and feeling tired.

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

- fainting, stroke, heart attack, irregular heartbeat, temporary decreased blood flow to parts of the brain, feeling of tightening of the throat, numb mouth, bleeding at the back of the eye,

double vision, reduced sharpness of vision, abnormal sensation in the eye, swelling of the eye or eyelid, small particles or spots in your vision, seeing halos around lights, dilation of the pupil of the eye, discolouration of the white of the eye, penile bleeding, presence of blood in semen, dry nose, swelling of the inside of the nose, feeling irritable and sudden decrease or loss of hearing.

From post-marketing experience cases of unstable angina (a heart condition) and sudden death have been reported rarely. Of note, most, but not all, of the men who experienced these side effects had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to Sildenafil.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sildenafil 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 and blister foil 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 Sildenafil Mylan contains

- The active substance is sildenafil. Each tablet contains 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 (see section 2 ‘Sildenafil Mylan contains 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.

Sildenafil Mylan 25 mg film-coated tablets are available in blister packs containing 1, 2, 4, 8 or 12 tablets.

Sildenafil Mylan 50 mg and 100 mg film-coated tablets are available in blister packs containing 1, 2, 4, 8, 12, 24, 36 or 48 tablets.

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 medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium: Sildenafil Viatrix 25 mg, 50 mg, 100 mg filmomhulde tabletten
Cyprus: Sildenafil Mylan 25 mg, 50 mg, 100 mg film-coated tablets
Czech Republic: Sildenafil Viatrix
Denmark: Sildenafil Viatrix
France: Sildenafil Viatrix 25 mg, 50 mg, 100 mg comprimé pelliculé
Germany: duraviril 50 mg, 100 mg Filmtabletten
Greece: Sildenafil Mylan 25 mg, 50 mg, 100 mg film-coated tablets
Hungary: Sildenafil Viatrix 100 mg filmtabletta
Iceland: Sildenafil Viatrix 25 mg, 50 mg, 100 mg Filmuhúðaðar töflur
Ireland: Sildenafil Mylan 25 mg, 50 mg, 100 mg film-coated tablets
Italy: Sildenafil Mylan
Luxembourg: Sildenafil Viatrix 25 mg, 50 mg, 100 mg comprimés pelliculés
Malta: Sildenafil Mylan 25 mg, 50 mg, 100 mg film-coated tablets
Norway: Sildenafil Viatrix
Portugal: Sildenafil Mylan
Slovakia: Sildenafil Viatrix 50 mg / 100 mg
Slovenia: Sildenafil Viatrix 50 mg, 100 mg filmsko obložene tablete
Spain: Sildenafil Viatrix 25 mg, 50 mg, 100 mg comprimidos recubiertos con película
The Netherlands: Sildenafil Mylan 25 mg, 50 mg, 100 mg, filmomhulde tabletten
United Kingdom (Northern Ireland): Sildenafil Mylan 25 mg, 50 mg, 100 mg film-coated tablets

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