

VIADIS® 25 mg, film-coated tablets

VIADIS® 50 mg, film-coated tablets

VIADIS® 100 mg, 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

1. What is VIADIS and in which case is it used ?
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3. How to take VIADIS ?
4. Possible side effects ?
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1. What is VIADIS and in which case is it used ?

VIADIS contains sildenafil, an active substance which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. Its action is to help relax the blood vessels of the penis, promoting blood flow into the penis, during sexual arousal. VIADIS will only help you get an erection if you have sexual stimulation. VIADIS is a treatment for adult men with erectile dysfunction, sometimes called impotence ; that is, when a man cannot achieve or maintain a sufficient erection for sexual activity.

2. What you need to know before you take VIADIS

Never take VIADIS

- If you are allergic to sildenafil or any of the other components of this medicine (listed in section 6).
- If you are taking medicines called nitrates, which can cause a potentially dangerous drop in your blood pressure. Tell your doctor if you are taking any of these medicines which are often used for the relief of angina attacks (or angina pectoris). If in doubt, ask your doctor or pharmacist for advice.

- If you are using any of the medicines known to donate nitric oxide such as Amyl Nitrite ("poppers"), as the combination can also cause a potentially dangerous drop in your blood pressure.

- If you are taking riociguat. This medicine is used to treat pulmonary arterial hypertension (PAH) (that is, high blood pressure in the pulmonary arteries) and chronic thromboembolic pulmonary hypertension (CPH) (that is, a high blood pressure in the pulmonary arteries due to the presence of persistent blood clots). PDE5 inhibitors, such as VIADIS, have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or if you are not sure talk to your doctor.

- If you have severe heart or liver problems.

- If you have recently had a stroke or heart attack or if your blood pressure is low.

- If you have certain rare inherited eye diseases (such as retinitis pigmentosa).

- If you have ever had vision loss due to anterior non-arteritic ischemic optic neuropathy (NAION).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking VIADIS :

- if you have sickle cell anemia (an abnormality of red blood cells), leukemia (cancer of blood cells), multiple myeloma (cancer of the bone marrow).

- if you have a penile deformity or Peyronie's disease.

- if you have heart problems. Your doctor should carefully assess whether your heart can tolerate the extra strain of sexual activity.

- if you currently have a stomach ulcer or bleeding disorders (such as hemophilia).

- if you experience sudden decrease or loss of vision, stop taking VIADIS and contact your doctor immediately.

You should not use VIADIS at the same time as any other oral or topical treatment for erectile dysfunction.

You should not use VIADIS at the same time as treatments for pulmonary arterial hypertension (PAH) containing sildenafil or other PDE5 inhibitors.

You should not take VIADIS if you do not have erectile dysfunction. You should not take VIADIS if you are a woman.

Special precautions for patients with kidney or liver problems

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

Children and adolescents

VIADIS is not indicated for people under 18 years of age.

Other medicines and VIADIS

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

VIADIS tablets may interact with certain medications, especially those used for angina pectoris. In the event of a medical emergency, you should tell your doctor, pharmacist or nurse that you have taken VIADIS and when you took it. Do not take VIADIS at the same time as other medicines unless your doctor tells you to.

You should not take VIADIS if you are taking medicines called nitrates, as the combination of these medicines can cause a potentially dangerous drop in your blood pressure. Always tell your doctor, pharmacist or nurse if you are taking any of these medicines which are often used for the relief of angina attacks (or angina pectoris).

You should not take VIADIS if you are taking any of the medicines known to donate nitric oxide such as amyl nitrite ("poppers") as this combination can also cause a potentially dangerous drop in your blood pressure.

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

If you are taking medicines known as protease inhibitors, especially for the treatment of HIV infection, your doctor may start your treatment with VIADIS with the lowest dose (25 mg).

Some patients taking an alpha-blocker medicine for the treatment of high blood pressure or an enlarged prostate may experience dizziness or drunkenness, which may be due to low blood pressure when switching rapidly to sitting or standing. Some patients have experienced these symptoms when taking VIADIS with alpha blockers. This occurs most often within 4 hours of taking VIADIS.

To reduce the probability of occurrence of these symptoms, you should be treated by a constant daily dose of alpha-blocker before you start treatment with VIADIS. Your doctor may start your treatment with VIADIS at a lower dose (25 mg).

VIADIS with food, drinks and alcohol

VIADIS can be taken with or without food. However, you may notice that VIADIS acts more slowly if you take it with a high fat meal.

Drinking alcohol may temporarily affect your ability to get an erection. To get the maximum benefit from your medicine, you are advised not to drink a lot of alcohol before taking VIADIS.

Pregnancy, breastfeeding and fertility

VIADIS is not indicated in women.

Driving and using machines

VIADIS may cause dizziness and may affect vision. Before you drive or use machines you should know how you react to VIADIS.

3. How to take VIADIS?

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if in doubt. The recommended starting dose is 50 mg.

You should not use VIADIS more than once a day.

Do not take sildenafil tablets along with sildenafil orodispersible tablets.

You should take VIADIS about an hour before you plan to have sex.

Swallow the tablet whole with a glass of water.

If you feel that the effect of VIADIS is too strong or too weak, talk to your doctor or pharmacist.

VIADIS will only help you get an erection if you have sexual stimulation. The VIADIS action period varies from person to person, but it normally takes half hour to an hour. You may find that VIADIS acts more slowly if you take it with a high fat meal.

If VIADIS does not allow you to get an erection, or if your erection is not long enough for you to have full sex, talk to your doctor.

If you take more VIADIS than you should

You may experience an increase in the number of side effects and their severity. Doses greater than 100 mg do not increase the effectiveness of the product.

Do not take more tablets than your doctor has told 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, pharmacist or nurse for more information.

4. Possible side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects reported with VIADIS are usually mild to moderate and of short duration.

If you experience any of the serious side effects listed below, stop taking VIADIS and contact your doctor immediately :

- An allergic reaction - this is **uncommon** (may affect up to 1 in 100 people) Symptoms may include sudden wheezing, difficulty breathing or dizziness, swelling of the eyelids, face, lips or throat.

- Chest pain - **uncommon**

If it happens during or after sex:

- Get into a semi-sitting position and try to relax.

- **Do not take nitrates** to relieve your chest pain.

- Prolonged erections, sometimes painful - this is rare (may affect up to 1 in 1,000 people)

If you have an erection that persists continuously for more than 4 hours, you should contact a doctor immediately.

- Sudden decrease in vision - this is **rare**

- Serious skin reactions - this is **rare**

Symptoms may include : severe peeling and swelling of the skin, blisters in the mouth, genital area and around the eyes, and fever.

- Convulsions or seizures - this is **rare**

Other side effects:

- A **very common side effect** (may affect more than 1 in 10 people) is headache.

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

nausea, flushing of the face, hot flashes (symptoms may include : a sudden feeling of heat in the upper body), indigestion, disturbances in color perception, blurred vision, visual disturbance, stuffy nose and dizziness.

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

vomiting, rash, eye irritation, bloodshot eyes / red eyes, eye pain, seeing flashes of light, visual shine, sensitivity to light, watery eyes, heartbeats, very strong heart, fast heartbeat, hypertension, hypotension, muscle pain, drowsiness, decreased sensitivity to touch, dizziness, ringing in the ears, dry mouth, blocked or blocked sinuses, inflammation of the nasal lining (symptoms may include runny nose, sneezing and stuffy nose), upper abdominal pain, gastroesophageal reflux disease (symptoms may be: heartburn, blood in the urine, pain in the arms or legs, nosebleeds, feeling hot and tired).

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

fainting, stroke, heart attack, irregular heartbeat, temporary decrease in blood supply to parts of the brain, feeling of tightness in the throat, numb mouth, bleeding at the back of the eye, double vision, decreased visual acuity, abnormal sensations in the eye, swelling of the eye or eyelid, small particles or spots in front of the eyes, seeing halos around lights, dilation of the pupil of the eye, change in the color of the white of the eye, bleeding from the penis, blood in the semen, dry nose, swelling of the inside of the nose, feeling irritable and sudden decrease or loss of hearing.

Based on post marketing experience, rare cases of unstable angina (heart disease) and sudden death have been reported. It should be noted that most, but not all, men who experienced these side effects had heart problems before taking this medicine. It is not possible to determine if these events were directly related to sildenafil.

Reporting side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This also applies to any side effects not mentioned in this leaflet. You can also report side effects directly via the national reporting system: CNPV (National Center of Pharmacovigilance). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store VIADIS

Store at a temperature not exceeding + 30 ° C.

Store in the original immediate packaging in order to protect from moisture.

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 after EXP. The expiration date refers to the last day of the month.

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

6. Content of the packaging and other information

What VIADIS contains

	VIADIS® 25 mg	VIADIS® 50 mg	VIADIS® 100 mg
Active substance : sildenafil (as citrate)	25 mg	50 mg	100 mg
Excipients	Microcrystalline cellulose, calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate, Opady II Blue RSG20411 (100mg, 50mg and 25mg), Opady II white HP R5F18378 (25mg)		

What does VIADIS look like and content of the outer packaging

This medicine is in the form of tablets in transparent PVC / aluminium Blisters.

B04 tablets.

Marketing Authorisation holder and Manufacturer

Les Laboratoires Médis.

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Supply and prescription Condition : List I

M.A.N:

VIADIS 25mg, B4 :9233661

VIADIS 50mg, B4 :9233662

VIADIS 100mg, B4 :9233663

This leaflet has been last reviewed : 03/2020



THIS IS A MEDICINE

- A medicine is a product but not like the others.
- A medicine is a product that affects your health and its consumption without compliance to the prescription exposes you to danger.
- Strictly follow your doctor's prescription and directions for use, follow the advice of your pharmacist.
- Your doctor and pharmacist are familiar with the medicine, its indications and contraindications.
- Do not stop treatment on your own initiative during the prescribed period.
- Do not take it again, do not increase the doses without consulting your doctor.

Keep medicines out of the reach of children