

Bijsluiter: informatie voor de patiënt

Sempavox 100 mg, tabletten

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

1. What [nationally completed name] is and what it is used for

[Nationally completed name] contains the active substance sildenafil which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) 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.

[Nationally completed name] will only help you to get an erection if you are sexually stimulated.

[Nationally completed name] 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 [nationally completed name]

Do not take [nationally completed name]

- 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 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 [nationally completed name] 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, pharmacist or nurse before taking [nationally completed name] - 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 [nationally completed name] and contact your doctor immediately.

You should not use [nationally completed name] with any other oral or local treatments for erectile dysfunction.

You should not use [nationally completed name] with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitors.

You should not take [nationally completed name] if you do not have erectile dysfunction.

You should not take [nationally completed name] if you are a woman.

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.

Children and adolescents

[Nationally completed name] should not be given to individuals under the age of 18.

Other medicines and [nationally completed name]

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

[Nationally completed name] tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell your doctor, pharmacist or nurse that you have taken [nationally completed name] and when you did. Do not take [nationally completed name] with other medicines unless your doctor tells you that you can.

You should not take [nationally completed name] if you are taking medicines called nitrates, as the combination of these medicines may lead to a dangerous fall in your blood pressure. Always tell your doctor, pharmacist or nurse 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 [nationally completed name] 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.

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 [nationally completed name] with alpha-blockers. This is most likely to happen within 4 hours after taking [nationally completed name]. To reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start [nationally completed name]. Your doctor may start you on a lower dose (25 mg) of sildenafil.

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

[Nationally completed name] with food and drink and alcohol

[Nationally completed name] can be taken with or without food. However, you may find that [nationally completed name] 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 [nationally completed name].

Pregnancy, breast-feeding and fertility

[Nationally completed name] is not indicated for use by women.

Driving and using machines

[Nationally completed name] can cause dizziness and can affect vision. You should be aware of how you react to [nationally completed name] before you drive or use machinery.

[nationally completed name] 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 [nationally completed name]

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 [nationally completed name] more than once a day.

Do not take [nationally completed name] tablets in combination with sildenafil containing orodispersible medicines.

You should take [nationally completed name] about one hour before you plan to have sex. Swallow the tablet with a glass of water.

The tablet can be divided into quarters for ease of swallowing. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses. In case the tablet cannot be

swallowed whole, the tablet may be split and all parts should be taken together (or sequentially) at the same time.

Dividing the tablets

Place the tablet on a hard, flat surface with the deeper scoreline facing upwards. Press with your thumb on the middle of the tablet and the tablet breaks into quarters.

If you feel that the effect of [nationally completed name] is too strong or too weak, talk to your doctor or pharmacist.

[Nationally completed name] will only help you to get an erection if you are sexually stimulated. The amount of time [nationally completed name] takes to work varies from person to person, but it normally takes between half an hour and one hour. You may find that [nationally completed name] takes longer to work if you take it with a heavy meal.

If [nationally completed name] 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 [nationally completed name] 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, pharmacist or nurse.

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 [nationally completed name] are usually mild to moderate and of a short duration.

If you experience any of the following serious side effects stop taking [nationally completed name] and seek medical help immediately:

- An allergic reaction - this occurs **uncommonly** (may affect up to 1 in 100 people)
Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.
- Chest pains - this occurs **uncommonly**
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.
- Prolonged and sometimes painful erections - this occurs **rarely** (may affect up to 1 in 1,000 people)
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 - this occurs **rarely**

- Serious skin reactions - this occurs **rarely**
Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever.
- Seizures or fits - this occurs rarely

Other side effects:

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

- headache

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

- nausea
- facial flushing
- hot flush (symptoms include a sudden feeling of heat in your upper body)
- indigestion
- colour tinge to vision; blurred vision; visual disturbance
- stuffy nose
- 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 or rapid heartbeat
- high or 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)
- presence of blood in urine
- pain in the arms or legs
- nosebleed
- feeling hot
- 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
- 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 [nationally completed name].

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 the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [nationally completed name]

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 expiry date refers to the last day of that month.

This medicinal product 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 further information

What [nationally completed name] contains

- The active substance is sildenafil. Each tablet contains 100 mg of sildenafil (as citrate).
- The other ingredients are: calcium hydrogen phosphate anhydrous (E 341), microcrystalline cellulose (E 460), copovidone, croscarmellose sodium (E 468), magnesium stearate (E 470b), saccharin sodium (E 954), indigo carmine

What [nationally completed name] looks like and contents of the pack

Light blue round slightly dotted tablets, with cross breaking notch on both sides and "100" debossed on one side.

Diameter: 12.5 mm

The tablets are packed in Polyvinylchloride-Aclar/Aluminium or PVC/PVDC/Aluminium blisters.

Pack sizes

1, 2, 4, 8 12 tablets

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen

Vergunninghouder:

Sandoz B.V.
Veluwezoom 22
1327 AH Almere
Nederland

Fabrikanten:

Lek Pharmaceuticals d.d.
Verovskova ulica 57
1526 Ljubljana
Slovenië

Lek S.A.
ul. Domaniewska 50 C
02-672 Warszawa
Polen

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1
39179 Barleben
Duitsland

Sandoz S.R.L
Str. Livezeni nr. 7A
RO-540474 Targu Mures
Roemenië

In het register ingeschreven onder:

Sempavox 100 mg, tabletten - RVG 121766

Dit geneesmiddel is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland	Sempavox 100 mg, tabletten
Oostenrijk	Sempavox 100 mg – Tabletten
België	Sempavox 100 mg tabletten
Duitsland	Sempavox 100 mg tabletten
Denemarken	Sempavox
Estland	Sempavox
Griekenland	Sempavox 100 mg δισκία
Spanje	Sildenafil Bexal 100 mg comprimidos EFG
Frankrijk	Sempavox 100 mg, comprime
Italië	Sempavox
Litouwen	Sempavox 100 mg tabletės

Letland Sempavox 100 mg tabletes
Potugal Sempavox
Slovenië Sempavox 100 mg tablete
Verenigd Koninkrijk Sempavox 100 mg Tablets

Deze bijsluiter is voor het laatst goedgekeurd in januari 2024