

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Via-Avenir 25 mg
Via-Avenir 50 mg
Via-Avenir 100 mg
Film-coated tablets for swallowing

Each tablet contains:

sildenafil citrate (equivalent to sildenafil) 25 mg, 50 mg, 100 mg

Inactive ingredients and allergens in this medicine: see section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours. This medicine is intended for adults over the age of 18 and is not intended for women.

1. What is this medicine intended for?

Treatment of impotence - erectile dysfunction.

Therapeutic group:

PDE5 enzyme inhibitor, causes dilation of blood vessels, thereby improving the blood flow into the penis during sexual stimulation.

2. Before using this medicine

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).
- you are intermittently or regularly taking organic nitrates, organic nitrites, or nitric oxide donors, such as amyl nitrite, in any form (such as certain medicines for treating angina pectoris).
- you are concomitantly taking guanylate cyclase stimulators (such as riociguat) for treating pulmonary hypertension.
- you have a severe heart or liver disease.
- you have recently had a stroke or a heart attack, or if you suffer from low blood pressure.
- you have a certain rare inherited eye disease (such as retinitis pigmentosa).
- you have or have had vision loss due to non-arteritic anterior ischemic optic neuropathy (NAION).

Special warnings about using this medicine

Before using Via-Avenir, tell your doctor if:

- you have sickle cell anemia (a disease of red blood cells), multiple myeloma (cancer of the bone marrow) or leukemia (cancer of the blood cells).
- you have a disease or deformity of your penis or Peyronie's Disease (scoliosis of the penis).
- you have heart problems, your doctor will check whether your heart can bear the additional strain associated with sexual intercourse.
- you have ever had a stomach ulcer, or a bleeding problem (such as hemophilia).
- you experience a sudden decrease or loss of vision; stop the treatment and contact your doctor immediately.
- Do not take this medicine if you do not have impotence (erectile dysfunction).
- Do not take this medicine if you are a woman.

Patients with kidney or liver diseases

If you have a kidney or liver disease, your doctor may decide on a lower dose for you.

Children and adolescents

The medicine is not intended for use under the age of 18.

Tests and follow-up

Before taking the medicine, the patient must undergo a comprehensive medical examination to make sure that the treatment is right for him and that he does not have cardiovascular problems (heart and blood vessels), since sexual activity in itself involves a certain degree of cardiac effort.

Drug interactions

A person who has taken Via-Avenir and requires any medical treatment must immediately tell the attending medical team that he has taken this medicine, in order to prevent a situation in which he will be treated with nitrates or other vasodilators.

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly inform your doctor or pharmacist if you are taking:

Via-Avenir in combination with other medicines may be harmful, particularly with medicines intended for treating chest pain (chest angina, angina pectoris). In case of a medical emergency, tell your doctor, nurse, or pharmacist that you have taken Via-Avenir and when you took it. Do not use Via-Avenir in combination with other medicines unless your doctor tells you that you can.

Do not use Via-Avenir if you are taking the following medicines:

- you are intermittently or regularly taking nitrates, as the combination with these types of medicines may lead to a dangerous decrease in your blood pressure. Consult your doctor if you are taking this type of medicines, which are usually used to treat angina pectoris (chest pain).
- medicines called nitric oxide donors such as amyl nitrite, as this combination may also lead to a dangerous decrease in your blood pressure.
- other medicines (oral or local administration) for treating impotence (erectile dysfunction) – the combination with Via-Avenir is forbidden.
- riociguat or other medicines for the treatment of pulmonary hypertension - the combination with Via-Avenir is forbidden.

Additional medicines:

- cimetidine (to reduce stomach acidity), ketoconazole (antifungal), erythromycin (antibiotic).
- HIV protease inhibitors for the treatment of AIDS (such as saquinavir, ritonavir) since they may increase the concentration of Via-Avenir in the blood. Your doctor may prescribe you the lowest dose.
- medicines of the alpha-blockers group such as doxazosin (for the treatment of hypertension or prostate enlargement) – due to concern that there will be a decrease in blood pressure. Combining this medicine with Via-Avenir may cause light-headedness or dizziness, which is caused by low blood pressure upon sitting or standing up quickly. This is most likely to happen within 4 hours after taking Via-Avenir. Your doctor may prescribe you the lowest dose.

Using this medicine and food

- The medicine can be taken with or without food; however, the onset of the medicine's effect may be delayed after a heavy meal.

Using this medicine and alcohol consumption

Alcohol consumption may temporarily impair your ability to get an erection. To achieve the maximal benefit from the medicine, you are advised not to drink excessive amounts of alcohol before taking the medicine.

Pregnancy and breastfeeding

This medicine is not intended for use in women.

Driving and using machines

Via-Avenir may cause dizziness and affect vision. You must pay attention to how you react to the medicine before you drive or operate machines.

Important information about some of this medicine's ingredients

This medicine contains sodium:

0.79 mg sodium in a Via-Avenir 25 mg tablet.

1.57 mg sodium in a Via-Avenir 50 mg tablet.

3.15 mg sodium in a Via-Avenir 100 mg tablet.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about your dosage or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine. The standard dosage is usually one tablet about an hour before sexual intercourse.

Do not take more than one tablet per day. Do not exceed the recommended dose.

Via-Avenir will help you to get an erection only if you are sexually stimulated. The time it takes for the medicine to start working varies from person to person, and it normally takes about half an hour to one hour. You may find that it takes the medicine longer to start working if you take it with a heavy meal.

If you feel that the medicine is too weak or too strong for you, consult your doctor or pharmacist.

If Via-Avenir does not help you to get an erection, or if the erection achieved does not last long enough for you to complete full sexual intercourse, consult your doctor.

Taking the tablets: Do not crush, split or chew. Swallow the medicine whole with some water.

If you accidentally take a higher dose

If you have taken an overdose, or if a child has accidentally swallowed some medicine, go to a hospital emergency room immediately and bring the medicine package with you. If you have taken an overdose, you may experience an exacerbation in side effects and in their severity.

Doses over 100 mg do not increase the efficacy of the medicine.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, use of Via-Avenir may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

The side effects reported in association with the use of Via-Avenir are usually mild to moderate and last a short time.

- **Stop taking this medicine and contact your doctor immediately in case of:** an allergic reaction – uncommon (may affect up to 1 in 100 people); the symptoms include sudden wheeziness, difficulty breathing or dizziness, swelling of the eyelids, face, lips or throat.
- chest pain during or after sexual intercourse – uncommon; If this happens to you during or after sexual intercourse, get in a semi-sitting position and try to relax. **Do not take nitrates to treat chest pain.**
- Prolonged and sometimes painful erection has been reported after using the medicine (rare frequency). If you experience an erection which lasts for more than 4 hours, contact a doctor immediately.

- A sudden decrease or loss of vision, rare (may affect up to 1 in 1,000 people), contact a doctor immediately.
- Severe skin reaction (a rare side effect) - symptoms may include severe peeling and swelling of the skin, blisters in the mouth, genitals, around the eyes, and fever.
- Fits or seizures (a rare side effect).

Additional side effects

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

Headache.

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

Dizziness, redness of the face, gastrointestinal disturbances, nasal congestion, seeing colors, blurred vision, vision disturbances, nausea, hot flushes (a sudden feeling of heat in the upper body).

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

Vomiting, rash, eye irritation/ pain, red eyes, sensitivity to light, seeing flashes of light, visual brightness, watery eyes, rapid or pounding heartbeat, hypertension, low blood pressure, muscle pain, sleepiness, reduced sense of touch, vertigo, ringing in the ears, dry mouth, blocked or congested sinuses, inflammation of the lining of the nose (symptoms include common cold, sneezing and nasal congestion), upper abdominal pain, gastro-esophageal reflux (symptoms include heartburn), feeling tired, presence of blood in urine, pain in the extremities, nosebleed, feeling hot.

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

Fainting, stroke, heart attack, heart rate disorders, sudden decrease in or loss of hearing, temporary decrease in blood flow to parts of the brain, feeling of constriction of the throat, , numb mouth, bleeding at the back of the eye, double vision, reduced visual acuity, abnormal sensation in the eye, swelling of the eye or eyelid, seeing small particles or spots, seeing halos around lights, dilation of the pupils, discoloration of the white of the eye, penile bleeding, presence of blood in semen, dry nose, swelling of the inside of the nose, irritability.

Side effects based on post-marketing reports:

Unstable angina and sudden death have been reported rarely. Most, but not all, of the men who experienced these side effects suffered from heart problems before taking this medicine. It is impossible to determine whether these effects were directly related to the use of the medicine.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:**
Store below 25°C.
Store in the original package.

6. Additional information

- **In addition to the active ingredient, this medicine also contains:**

Microcrystalline cellulose, dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, polyvinilic alcohol, polyethylene glycol 3350, titanium dioxide, talc, indigo carmine aluminum lacquer.

- **What the medicine looks like and contents of the pack:**
Via-Avenir 25 mg – oval, blue tablet imprinted on one side with “-”
Via-Avenir 50 mg – oval, blue tablet with no imprinting
Via-Avenir 100 mg – oval, blue tablet imprinted on one side with “+”
This medicine is supplied in packs of 2, 4, and 8 tablets packaged in blister trays.
- **Registration holder and importer:**
BioAvenir Ltd., 1 David HaMelech St., Herzliya Pituah 4666101, Israel.
- **Manufacturer:**
Tecnimed España Industria Farmaceutica Ltd., Madrid, Spain.
- **Registration numbers of the medicine in the Ministry of Health’s National Drug Registry:**
Via-Avenir 25 mg - 147 70 33416
Via-Avenir 50 mg - 147 71 33414
Via-Avenir 100 mg - 147 72 33415

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