

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Vardenafil Inovamed 10 mg Vardenafil Inovamed 20 mg Film-coated tablets

Each tablet of Vardenafil Inovamed 10 mg contains: Vardenafil (as hydrochloride trihydrate) 10 mg
Each tablet of Vardenafil Inovamed 20 mg contains: Vardenafil (as hydrochloride trihydrate) 20 mg
For a list of the inactive ingredients and allergens in the preparation, see section 6 – "Additional information" and in section 2 – "Important information about some of the ingredients of the medicine".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Vardenafil Inovamed is intended for the treatment of erectile dysfunction in men.

At least one in ten adult men occasionally suffers from erectile dysfunction, that is, difficulty to obtain or maintain an erection. This can be caused by physical or psychological causes or by a mixture of both. In any case, due to muscle and blood vessel changes, not enough blood reaches the penis to make it hard and keep it hard.

Therapeutic class: vardenafil belongs to a group of medicines called PDE5 enzyme inhibitors. The inhibition of this enzyme leads to the relaxation of the blood vessel wall muscles in the penis, which allows blood flow to the penis, thus enabling an erection.

Vardenafil Inovamed only works when there is a sexual stimulation, and it allows the erection to last long enough to allow satisfying sexual activity.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient vardenafil or to any of the additional components the medicine contains. For the list of inactive ingredients, see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine". Signs of an allergic reaction include rash, itching, swollen face or lips and shortness of breath.
- You have ever developed severe skin rash or peeling of the skin, blistering and/or mouth sores after taking Vardenafil Inovamed.
- You are taking medicines containing nitrates, such as glyceryl trinitrate for treatment of angina pectoris or nitric oxide donors, such as amyl nitrite. Taking these medicines with Vardenafil Inovamed may seriously affect your blood pressure.
- You are taking ritonavir or indinavir, medicines used to treat human immunodeficiency virus (HIV) infections.
- You are taking ketoconazole or itraconazole, antifungal medicines.
- You are taking erythromycin or clarithromycin, macrolide antibiotics.
- You are taking alpha blockers, a type of medicine used to treat high blood pressure and enlargement of the prostate (such as benign prostatic hyperplasia).
- You suffer from a severe heart or liver problem.
- You are on kidney dialysis.
- You have recently had a stroke or a heart attack (in the past six months).
- You suffer or have suffered in the past from low blood pressure.
- Your family has a history of degenerative eye diseases (such as retinitis pigmentosa).
- You have ever had a condition involving loss of vision due to damage to the optic nerve caused by insufficient blood supply, known as non-arteritic ischemic optic neuropathy (NAION).
- 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 enzyme inhibitors, such as Vardenafil Inovamed, have been shown to increase the hypotensive effects of the preparation riociguat. If you are taking riociguat or if you are unsure, tell your doctor.

Do not use Vardenafil Inovamed if you are a woman.
Special warnings regarding the use of the medicine:

Talk to the doctor or pharmacist before taking Vardenafil Inovamed.

Before treatment with Vardenafil Inovamed, tell the doctor if:

- You have a heart problem. Having sexual intercourse may be dangerous for you.
- You suffer from irregular heart beat (cardiac arrhythmia) or inherited heart diseases affecting your ECG.
- You have a physical condition affecting the shape of the penis. This includes conditions called angulation, curvature of the penis (Peyronie's disease) and fibrosis (thickening and scarring of the cavernous tissue).
- You have a disease that may cause erections that won't go away (priapism – prolonged erection). These include sickle cell disease, multiple myeloma and leukemia.
- You suffer from stomach ulcers (also called gastric or peptic ulcer).
- You suffer from a bleeding disorder (such as hemophilia).
- You are using any other medicines for erection difficulties (see also below "Drug interactions"). If you experience a sudden decrease in vision or sudden loss of vision or if your vision is distorted or dimmed while you are taking Vardenafil Inovamed, stop taking Vardenafil Inovamed and refer to your doctor immediately.

Serious skin reactions which may be life-threatening and even fatal, including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in association with vardenafil treatment. Stop using Vardenafil Inovamed and immediately refer to the doctor to receive treatment if you notice any of the symptoms related to these serious skin reactions, as described in section 4. If you develop these serious skin reactions, the doctor will instruct you not to use Vardenafil Inovamed again.

The elderly (aged 65 and above)

Before using the medicine, tell the doctor if you are elderly.

Patients with kidney or liver problems

Before using the medicine, tell the doctor if you suffer from kidney or liver problems.

Children and adolescents

Vardenafil Inovamed is not intended for use in children or adolescents under the age of 18.

Tests and follow-up

Before using Vardenafil Inovamed, you should undergo a thorough medical examination in order to diagnose the problem and its causes and to make sure that the treatment is appropriate. The doctor will consider your cardiovascular condition, since sexual activity is associated with a certain degree of cardiac risk.

Drug interactions

If you are taking, have recently taken or might take other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially inform the doctor or pharmacist if you are taking:

- Nitrates, medicines for the treatment of angina pectoris or nitric oxide donors, such as amyl nitrite. Taking these medicines with Vardenafil Inovamed may seriously affect your blood pressure.
- A medicine for treatment of heart rate disorders (arrhythmias), such as quinidine, procainamide, amiodarone or sotalol.
- Ritonavir or indinavir, medicines for treatment of HIV (AIDS).
- Ketoconazole or itraconazole, antifungal medicines.
- Erythromycin or clarithromycin, macrolide antibiotics.
- Alpha blockers, a type of medicine used to treat high blood pressure and enlargement of the prostate (such as benign prostatic hyperplasia).
- Riociguat, for treatment of certain types of pulmonary hypertension.
- Nifedipine, a medicine from the group of calcium channel blockers.

For more details, please see section 2 "Do not use this medicine if".

Do not use Vardenafil Inovamed film-coated tablets in combination with any other treatment for erectile dysfunction.

Use of the medicine and food

Vardenafil Inovamed can be taken with or without food, but preferably not after a heavy or high-fat meal, as this may delay the effect of the medicine. Do not drink grapefruit juice or eat grapefruit when you use Vardenafil Inovamed. This may interfere with the usual effect of the medicine.

Use of the medicine and alcohol consumption

An alcoholic drink can worsen erection difficulties.
Pregnancy and breastfeeding

Vardenafil Inovamed is not intended for use by women.

Driving and operating machinery

Vardenafil Inovamed may make some people feel dizzy or affect their vision. If you feel dizzy or if your vision is affected after taking Vardenafil Inovamed, do not drive and do not operate any devices or machines.

Important information about some of the ingredients of the medicine

Vardenafil Inovamed 20 mg tablets contain the yellow coloring agent sunset yellow FCF aluminium lake (E110), which may cause allergic reactions.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The dosage and treatment regimen will be determined only by the doctor.

The generally recommended dosage is 10 mg. Take one tablet about 25 to 60 minutes before sexual activity.

For conditions that require treatment at a dosage lower than 10 mg, the doctor will consider treatment with an alternative medical preparation.

With the help of sexual stimulation, you may obtain an erection within 25 minutes to 4-5 hours after taking Vardenafil Inovamed.

Do not take Vardenafil Inovamed film-coated tablets with any other medicines or dosage forms for erection difficulties.

Do not take Vardenafil Inovamed more than once a day.

Tell your doctor if you think that Vardenafil Inovamed is too strong or too weak. Depending on the degree to which the medicine affects you, the doctor may suggest switching to a different dosage of Vardenafil Inovamed or to an alternative treatment for erection difficulties.

Special populations

The elderly: dose adjustment is not required in elderly patients. However, an increase to a maximum dose should be carefully considered by the doctor, since tolerability may be lower in elderly patients.

Liver function disorders: in patients with mild and moderate liver disorders, the doctor will consider an alternative treatment. Vardenafil Inovamed must not be used in patients with a severe liver disorder.
Kidney function disorders: no dose adjustment is required in patients with a mild to moderate kidney function disorder. In patients with a severe kidney function disorder, the doctor will consider an alternative treatment.

Children and adolescents: Vardenafil Inovamed is not intended for use in children or adolescents under the age of 18.

Do not exceed the recommended dose.

How to take the medicine

Swallow one tablet with a glass of water.

No information is available regarding crushing/halving/chewing.

If you accidentally took a higher dosage, refer to a doctor.

Men who take too much Vardenafil Inovamed may experience more side effects or may suffer from severe back pain.

If you took an overdose or if a child accidentally swallowed this medicine, go to the doctor or to a hospital emergency room immediately and take the package of the medicine with you.

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

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Vardenafil Inovamed may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Most of the effects are mild or moderate.
Stop taking Vardenafil Inovamed and contact your doctor immediately if you suffer from partial, sudden, temporary or permanent decrease in vision or loss of vision or distorted, dimmed or blurred central vision in one or both eyes.

Additional side effects

There have been reports of sudden decrease in or loss of hearing.

In men who have taken vardenafil, there have been reports of cases of sudden death, fast or altered heart beat, heart attack, chest pain and cerebral circulation problems (including temporary decrease in blood flow to parts of the brain and bleeding in the brain). Most of the men who experienced these side effects suffered from heart problems before taking this medicine. It cannot be determined whether these events were directly related to vardenafil.

The chance of suffering from a side effect is described by the following categories:

Very common side effects – effects that occur in more than one user out of ten:

- Headache
- Common side effects – effects that occur in 1-10 users out of 100:
 - Dizziness
 - Flushing
 - Blocked or runny nose
 - Indigestion

Uncommon side effects – effects that occur in 1-10 users out of 1,000:

- Swelling of the skin and mucous tissue, including swelling of the face, lips or throat
- Sleep disorder
- Numbness and impaired perception of touch
- Sleepiness
- Effects on vision, redness of the eye, effects on color vision, eye pain and discomfort, sensitivity to light
- Ringing in the ears, vertigo (spinning dizziness)
- Fast heartbeat or pounding heart
- Breathlessness
- Stuffy nose
- Acid reflux (heartburn), inflammation of the lining of the stomach (gastritis), abdominal pain, diarrhea, vomiting, nausea, dry mouth
- Increase in liver enzyme levels in your blood
- Rash, reddened skin
- Back pain or muscle pain, increase in muscle enzyme (creatine phosphokinase) in the blood, muscle stiffness
- Prolonged erections
- General malaise

Rare side effects – effects that occur in 1-10 users out of 10,000:

- Inflammation of the eyes (conjunctivitis)
- An allergic reaction
- Anxiety
- Fainting
- Amnesia
- Seizure
- Increased pressure in the eye (glaucoma), increased lacrimation
- Effects on the heart (such as heart attack, changes in heart beat or angina pectoris)
- High or low blood pressure
- Nose bleeding
- Effect on the results of blood tests to check liver function
- Skin sensitivity to sunlight
- Painful erections
- Chest pain
- Temporary decrease in blood flow to parts of the brain

Very rare side effects – effects that occur in less than one user out of 10,000 or side effects with unknown frequency (effects whose frequency has not yet been determined):

- Blood in the urine (hematuria)
- Bleeding from the penis (penile hemorrhage)
- Presence of blood in the semen (hematospermia)
- Sudden death
- Bleeding in the brain
- Reddish non-raised, target-like or circular patches on the body, sometimes with blisters in the center, peeling of the skin, ulcers in the mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Distorted, dimmed or blurred central vision or sudden decrease in vision.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by entering the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store this medicine below 30°C.
- Do not discard medicines in wastewater or a domestic trash can. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose, crospovidone type B, hypromellose type 2910, titanium dioxide (E171), magnesium stearate, silica colloidal anhydrous, macrogol type MW400, iron oxide yellow (E172).

Vardenafil Inovamed 10 mg film-coated tablets also contain:

Iron oxide red (E172)

Vardenafil Inovamed 20 mg film-coated tablets also contain:

Sunset yellow FCF aluminium lake (E110)

What does the medicine look like and what are the contents of the package?

Vardenafil Inovamed 10 mg: light orange, round, biconvex film-coated tablets.

Vardenafil Inovamed 20 mg: orange, round, biconvex film-coated tablets.

Size of the package:

The medicine is supplied in the following packaging: carton packages containing trays/blisters with 4 or 8 tablets.

The number of tablets in each package appears on the carton package.

Not all package sizes may be marketed.

License holder and importer: Inovamed Ltd., P.O. Box 62, Even Yehuda.

Manufacturer: Zakłady Farmaceutyczne Polpharma S.A., Poland.
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Registration numbers of the medicines in the national drug registry of the Ministry of Health:
Vardenafil Inovamed 10 mg – 168-12-36000
Vardenafil Inovamed 20 mg – 168-13-36001