

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

## Vardenafil Inovamed 5 mg

## Vardenafil Inovamed 10 mg

## Vardenafil Inovamed 20 mg

### Film-coated tablets

Each Vardenafil Inovamed 5 mg tablet contains:  
Vardenafil (as hydrochloride trihydrate) 5 mg

Each Vardenafil Inovamed 10 mg tablet contains:  
Vardenafil (as hydrochloride trihydrate) 10 mg

Each Vardenafil Inovamed 20 mg tablet contains:  
Vardenafil (as hydrochloride trihydrate) 20 mg

For the list of inactive and allergenic ingredients in the preparation, see section 6 "Further information" and "Important information about some of the ingredients in the medicine" in section 2.

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. 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 sometimes has erectile dysfunction, namely, difficulty achieving and maintaining an erection. There may be physical or psychological causes, or a mixture of both. Whatever the cause is, due to muscle and blood vessel changes, not enough blood reaches the penis to make and keep it hard.

**Therapeutic group:** Vardenafil belongs to a group of medicines called PDE5 enzyme inhibitors.

Inhibition of the enzyme results in relaxation of the muscles in the walls of the blood vessels of the penis; this enables flow of blood into the penis, and thereby, to erection.

Vardenafil Inovamed only works when there is sexual stimulation, and enables the erection to last long enough to enable satisfactory sexual performance.

**2. BEFORE USING THE MEDICINE****Do not use this medicine if:**

- you are sensitive (allergic) to the active ingredient vardenafil or any of the additional ingredients contained in this medicine. For the list of inactive ingredients, see section 6 "Further information" and in section 2 "Important information about some of the ingredients in the medicine". Signs of an allergic reaction include a rash, itching, swollen face or lips and shortness of breath.
- you are taking medicines containing nitrates, such as glycerol trinitrate to treat 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 over 75 years of age and are taking ketoconazole or itraconazole, anti-fungal medicines.
- you have a severe heart or liver problem.
- you undergo kidney dialysis.
- you have recently had a stroke or heart attack (in the last half a year).
- you have or have had 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 from 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 pulmonary hypertension secondary to chronic thromboembolic events (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 riociguat. If you are taking riociguat or are unsure, tell your doctor.

**Special warnings regarding use of this 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 sex may be dangerous for you.
- you have an irregular heartbeat (*cardiac arrhythmia*) or inherited heart diseases affecting your electrocardiogram (ECG).
- you have a physical condition affecting the shape of the penis. This includes conditions called angulation, Peyronie's disease and fibrosis (thickening and scarring of the erectile tissue).
- you have an illness that can cause erections which do not go away (priapism – prolonged erection). These include sickle cell anemia, multiple myeloma and leukemia.
- you have stomach ulcers (also called *gastric* or *peptic ulcers*).
- you have a bleeding disorder (such as *hemophilia*).
- you are using any other medicines for erectile difficulties, including Levitra 10 mg orodispersible tablets (also see section "Drug interactions" below).
- you experience a sudden decrease or loss of vision. Stop taking Vardenafil Inovamed and contact your doctor immediately.

**Children and adolescents**

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

**Drug interactions**

**If you are taking, or have recently taken other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist.** In particular, inform the doctor or pharmacist if you are taking:

- Nitrates, medicines to treat angina pectoris, or nitric oxide donors, such as amyl nitrite. Taking these medicines with Vardenafil Inovamed could seriously affect your blood pressure.
- A medicine for the treatment of arrhythmias, such as quinidine, procainamide, amiodarone or sotalol.
- Ritonavir or indinavir, medicines to treat HIV (AIDS).
- Ketoconazole or itraconazole, anti-fungal medicines.
- Erythromycin or clarithromycin, macrolide antibiotics.
- Alpha-blockers, a type of medicine used to treat high blood pressure and enlargement of the prostate (e.g., *benign prostatic hyperplasia*).
- Riociguat to treat certain types of pulmonary hypertension – do not take Vardenafil Inovamed. For further details, see section 2 "Do not use the medicine if".

Do not use Vardenafil Inovamed film-coated tablets combined with any other treatment for erectile dysfunction, including Levitra 10 mg orodispersible tablets.

**Use of the medicine and food**

Vardenafil Inovamed can be taken with or without food, but it is preferable not to take it after a heavy or fat-rich meal, since it could delay the effect of the medicine.

Do not drink grapefruit juice when you use Vardenafil Inovamed. This may disrupt the usual effect of the medicine.

**Use of the medicine and alcohol consumption**

Alcoholic beverages can worsen erectile difficulties.

**Pregnancy and breastfeeding**

Vardenafil Inovamed is not intended for use by women.

**Driving and using 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 or operate any tools or machinery.

**Important information about some of the ingredients in the medicine**

Vardenafil Inovamed 20 mg tablets contain sunset yellow aluminum lake (E110) dye, which may cause allergic reactions.

**3. HOW SHOULD YOU USE THE MEDICINE?**

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

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

The recommended dosage is usually 10 mg.

Take one tablet approximately 25 to 60 minutes before sexual activity.

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

**Do not take Vardenafil Inovamed film-coated tablets** with other medicines or any other dosage forms for erectile dysfunction (e.g., Levitra 10 mg orodispersible tablets).

**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 effect it has on you, the doctor may suggest switching to an alternative dosage form of vardenafil at a different dosage of the medicine for erectile difficulties.

**Do not exceed the recommended dosage.**

**Method of administration**

Swallow one tablet with a glass of water.

There is no information regarding crushing/halving/chewing.

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

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

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

**4. SIDE EFFECTS**

As with any medicine, use of Vardenafil Inovamed may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Most of the effects are mild to moderate.

**Stop taking Vardenafil Inovamed and contact your doctor immediately if you suffer from partial, sudden temporary or permanent reduced vision or loss of vision in one or both eyes.**

**Additional side effects**

There are reports of sudden reduction or loss of hearing.

In men who took vardenafil, there have been reports of sudden death, rapid or changing pulse, heart attack, chest pain, and problems with blood flow to the brain (including temporary reduction in blood flow to parts of the brain and bleeding in the brain). Most 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 according to the following categories:

**Very common side effects – effects that occur in more than 1 user in 10:**

- headache

**Common side effects – effects that occur in 1-10 in 100 users:**

- dizziness
- flushing
- blocked or runny nose
- digestion difficulties

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

- skin and mucosal swelling, including swelling of the face, lips or throat
- sleep disturbance
- numbness and impaired perception of touch
- sleepiness
- effects on vision, redness of the eye, effects on color vision, eye pain and discomfort, light sensitivity
- ringing in the ears, vertigo
- fast heartbeat or pounding heart
- breathlessness
- congested nose
- acid reflux (heartburn), gastritis, abdominal pain, diarrhea, vomiting, nausea, dry mouth
- raised levels of liver enzymes in your blood
- rash, reddened skin
- back or muscle pain, increase muscle enzyme (*creatinine phosphokinase*) in the blood, muscle stiffness
- prolonged erections
- malaise

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

- inflammation of the eyes (*conjunctivitis*)
- allergic reaction
- anxiety
- fainting
- amnesia
- seizure
- increased pressure in the eye (*glaucoma*), hyperlacrimation
- effects on the heart (such as heart attack, altered heartbeat or *angina pectoris*)
- high or low blood pressure
- nosebleed
- effect on results of blood tests to check liver function
- sensitivity of the skin to sun light
- painful erections
- chest pain
- temporary decrease in blood flow to parts of the brain

**Very rare side effects – effects occurring in less than one user in 10,000 or side effects of unknown frequency (effects whose frequency has not been determined):**

- blood in the urine (*hematuria*)
- penile bleeding (*penile hemorrhage*)
- presence of blood in the semen (*hematospermia*)
- sudden death
- bleeding in the brain

**If a side effect occurs, if one of the side effects worsens, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects of drug treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)), that directs you to the online form for reporting side effects, or by entering the link: <http://sideeffects.health.gov.il>

**5. HOW SHOULD THE MEDICINE BE STORED?**

• **Avoid poisoning!** This medicine, and any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

• Do not use the medicine after the expiry date (exp. date) that appears 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 the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

**6. FURTHER INFORMATION**

In addition to the active ingredient, the medicine also contains: Microcrystalline cellulose, crospovidone type B, magnesium stearate, silica colloidal anhydrous, hypromellose type 2910, titanium dioxide (E171), iron oxide yellow (E172), macrogol type MW400.

**Vardenafil Inovamed 5 mg and 10 mg film-coated tablets also contain:**  
Iron oxide red.

**Vardenafil Inovamed 20 mg film-coated tablets also contain:**  
Sunset yellow FCF aluminum lake (E110).

**What the medicine looks like and the contents of the package:**

**Vardenafil Inovamed 5 mg:** round, biconvex, brownish-orange, film-coated tablets.

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

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

**Package size:**

The medicine is supplied in the following pack: carton packs containing trays (blisters) with 4, 8 tablets.

The number of tablets in each pack is indicated on the carton package.

Not all package sizes may be marketed.

**Registration holder and address:** Inovamed Ltd., 55 Beer Ganim St., P.O.B. 62, Even Yehuda 40500

**Manufacturer and address:** Zakłady Farmaceutyczne Polpharma S.A. 83-200 Starogard Gdanski, Poland

Revised in March 2022 in accordance with the Ministry of Health guidelines

**Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:**

Vardenafil Inovamed 5 mg: 168-11-35973

Vardenafil Inovamed 10 mg: 168-12-36000

Vardenafil Inovamed 20 mg: 168-13-36001