

## **Package leaflet: Information for the patient**

**Vardenafil 5 mg film-coated tablets**  
**Vardenafil 10 mg film-coated tablets**  
**Vardenafil 20 mg film-coated tablets**

**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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

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

#### **1. What Vardenafil is and what it is used for**

Vardenafil contains the active substance vardenafil, a member of a class of medicines called phosphodiesterase type 5 inhibitors. They are used for the treatment of erectile dysfunction in adult men, a condition which implies difficulties in getting or keeping an erection.

At least one in ten men has trouble getting or keeping an erection at some time. 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 stays in the penis to make it hard or to keep it hard.

Vardenafil will only work when you are sexually stimulated. It reduces the action of the natural chemical in your body which makes erections go away. Vardenafil allows an erection to last long enough for you to satisfactorily complete sexual activity.

#### **2. What you need to know before you take Vardenafil**

##### **Do not take Vardenafil:**

- if you are allergic to vardenafil or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include a rash, itching, swollen face or lips and shortness of breath
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Vardenafil Mylan.
- if you are taking medicines containing nitrates, such as glycerol trinitrate for angina, or nitric oxide donors, such as amyl nitrite. Taking these medicines with vardenafil could seriously affect your blood pressure
- if you are taking ritonavir or indinavir, medicines used to treat human immunodeficiency virus (HIV) infection
- if you are over 75 years of age and are taking ketoconazole or itraconazole, anti-fungal medicines

- if you have a severe heart or liver problem
- if you are having kidney dialysis
- if you have recently had a stroke or heart attack
- if you have or have had low blood pressure
- if your family has a history of degenerative eye diseases (such as retinitis pigmentosa)
- if 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)
- 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 vardenafil have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Vardenafil:

- if you have heart trouble. It may be risky for you to have sex
- if you suffer from irregular heart beat (cardiac arrhythmia) or inherited heart diseases affecting your electrocardiogram
- if you have a physical condition affecting the shape of the penis. This includes conditions called angulation, Peyronie's disease and cavernosal fibrosis
- if you have an illness that can cause erections which won't go away (priapism). These include sickle cell disease, multiple myeloma and leukaemia
- if you are elderly
- if you have low levels of potassium in your blood
- if you have stomach ulcers (also called gastric or peptic ulcers)
- if you have a bleeding disorder (such as haemophilia)
- if you are using any other treatments for erection difficulties, see section 'Other medicines and Vardenafil'.

Your doctor will check your medical history and give you a physical examination before you start taking Vardenafil to try and identify the cause of the erectile dysfunction.

### **During treatment**

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, have been reported in association with vardenafil treatment. Stop using Vardenafil Mylan and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

If you experience sudden decrease or loss of vision or your vision is distorted or dimmed while you are taking Vardenafil Mylan, stop taking Vardenafil and contact your doctor immediately.

### **Children and adolescents**

Vardenafil is not intended for use by children or adolescents under 18.

### **Other medicines and Vardenafil**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Do not take Vardenafil with the following medicines:

- nitrates, medicines for angina such as nicorandil or nitroglycerin, or nitric oxide donors, such as amyl nitrite. Taking these medicines with Vardenafil could seriously affect your blood pressure
- riociguat
- ritonavir or indinavir, medicines for HIV.

Some medicines may cause problems, especially these:

- medicine for the treatment of arrhythmias, such as quinidine, procainamide, amiodarone or sotalol
- 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 (as benign prostatic hyperplasia) such as tamsulosin, terazosin and alfuzosin
- nifedipine, used to treat blood pressure and angina.

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

#### **Vardenafil with food, drink and alcohol**

- You can take Vardenafil with or without food – but preferably not after a heavy or high-fat meal as this may delay the effect.
- Do not drink grapefruit juice when you use Vardenafil. It can interfere with the usual effect of the medicine.
- Alcoholic drink can make erection difficulties worse.

#### **Pregnancy and breast-feeding**

Vardenafil is not for use by women.

#### **Driving and using machines**

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

### **3. How to take Vardenafil**

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 dose is 10 mg.

Take a Vardenafil tablet about 25 to 60 minutes before sexual activity. With sexual stimulation, you may achieve an erection anywhere from 25 minutes up to four to five hours after taking Vardenafil:

- Swallow one tablet with a glass of water.

**Do not take Vardenafil** more than once a day.

Tell your doctor if you think Vardenafil is too strong or too weak. He or she may suggest a switch to a different dose, depending on how well it works for you.

If you have liver or severe kidney problems, you may start with a lower dose.

#### **If you take more Vardenafil than you should**

Men who take too much Vardenafil may experience more side effects or may get severe back pain. If you take more Vardenafil than you should, tell your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most of the effects are mild or moderate.

Cases of sudden death, fast or altered heart beat, heart attack, chest pain, and trouble in cerebral circulation (including temporarily decreased blood flow to parts of the brain and bleeding in the brain) have been reported in men taking vardenafil. Most 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 vardenafil.

**Contact your doctor immediately and do not take Vardenafil if you notice the following:**

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

- swelling of the face, mouth, lips, tongue, throat or neck causing difficulty breathing or swallowing.

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

- seizures
- sudden chest pain which may spread to the neck or arm, with shortness of breath and a clammy feeling. These may be signs of a heart attack.
- abnormally fast heart beats
- heavy or pressing sensation on your chest with chest pain and an increased shortness of breath on exercise (these may be signs of problems with your heart such as angina)
- temporarily decreased blood flow to parts of the brain.

**Not known** (cannot be estimated from the available data):

- partial, sudden, temporary or permanent decrease or loss of vision, or distorted, dimmed, or blurred central vision in one or both eyes has been experienced by patients
- sudden decrease or loss of hearing
- sudden death
- bleeding in the brain
- bleeding from the penis.

Patients who have taken medicines similar to Vardenafil have also experienced the following:

- numbness or weakness in the arms or legs, having one side of the face drop, headache, dizziness, confusion, sight or speech problems, one side of the face may be dropped. These are signs that the blood supply to the brain is cut off resulting in a stroke or if these signs are temporary, a transient ischaemic attack.

**Other side effects include:**

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

- headache.

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

- dizziness
- flushing
- blocked or runny nose
- indigestion.

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

- sleep problems
- numbness, pain or the sensation of pins and needles in your arms, legs, hands or feet
- sleepiness
- problems with your sight, redness of the eye, effects on colour vision, eye pain and discomfort, light sensitivity
- ringing in the ears (tinnitus); a spinning sensation when standing or sitting (vertigo)

- fast heart beat or pounding heart
- breathlessness
- stuffy nose
- acid reflux, inflamed stomach (gastritis). You may have pain, nausea, vomiting, vomiting blood or have blood in your stools
- gut or stomach pain, diarrhoea, vomiting, feeling sick (nausea), dry mouth
- raised levels of liver enzymes in your blood, which can be seen in a blood test
- rash, reddened skin
- back or muscle pain
- increase in blood of a muscle enzyme (creatine phosphokinase), which can be seen in a blood test
- muscle stiffness, cramping
- prolonged erections
- feeling unwell.

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

- inflammation of the eyes (conjunctivitis)
- allergic reaction
- anxiety
- fainting
- amnesia
- increased pressure in the eye, watery eyes
- high or low blood pressure
- nose bleed
- sensitivity of the skin to sun light
- painful erections, which can last for a long time
- chest pain.

**Not known** (frequency cannot be estimated from the available data):

- blood in the urine (haematuria)
- presence of blood in the semen (haemospermia).
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of 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 of vision

### **Reporting of side effects**

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Vardenafil**

This medicine does not require any special storage conditions.

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.

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 other information**

### **What Vardenafil contains**

The active substance is vardenafil.

Each Vardenafil 5 mg film-coated tablet contains 5 mg of vardenafil (as hydrochloride trihydrate).

Each Vardenafil 10 mg film-coated tablet contains 10 mg of vardenafil (as hydrochloride trihydrate).

Each Vardenafil 20 mg film-coated tablet contains 20 mg of vardenafil (as hydrochloride trihydrate).

The other ingredients of the tablets are:

Tablet-core: microcrystalline cellulose, crospovidone, colloidal anhydrous silica, magnesium stearate.

Film-coating: hypromellose, titanium dioxide (E171), macrogol, iron oxide yellow (E172), iron oxide red (E172).

### **What Vardenafil looks like and contents of the pack**

- Vardenafil 5 mg: A brown film coated, round shaped, biconvex, bevelled edge tablet marked with 'M5' on one side of the tablet and 'VL' on the other side.
- Vardenafil 10 mg: A brown film coated, round shaped, biconvex, bevelled edge tablet marked with 'M' over '10' on one side of the tablet and 'VL' on the other side.
- Vardenafil 20 mg: A brown film coated, round shaped, biconvex, bevelled edge tablet marked with 'M' over '20' on one side of the tablet and 'VL' on the other side.

The tablets are provided in blister packs containing 2, 4, 8, 12 or 20 tablets and in perforated unit dose blister packs of 4 x 1 and 8 x 1 tablets. Vardenafil 20 mg tablets are also available in perforated unit dose blister packs of 12 x 1 and 20 x 1 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Mylan, Potters Bar, Hertfordshire,  
EN6 1TL United Kingdom

### **Manufacturers**

McDermott Laboratories Limited T/A Gerard Laboratories, T/A Mylan Dublin, Unit 35/36 Baldoyle Industrial Estate, Grange road, Dublin 13, Ireland

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Generics [UK] Limited, Station Close, Potters Bar, EN6 1TL, United Kingdom.

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