

## Package Leaflet: Information for the user

### **Vardenafil Waymade 5 mg film-coated tablets** **Vardenafil Waymade 10 mg film-coated tablets** **Vardenafil Waymade 20 mg film-coated tablets** vardenafil

**Read all of this leaflet carefully before you start using 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 Waymade is and what it is used for
2. What you need to know before you take Vardenafil Waymade
3. How to take Vardenafil Waymade
4. Possible side effects
5. How to store Vardenafil Waymade
6. Contents of the pack and other information

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

Vardenafil Waymade contains 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 and keep it hard.

Vardenafil Waymade 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 Waymade allows an erection to last long enough for you to satisfactorily complete sexual activity.

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

##### **Do not take Vardenafil Waymade 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.
- are taking medicines containing nitrates, such as glycerol trinitrate for angina, or nitric oxide donors, such as amyl nitrite. Taking these medicines with Vardenafil Waymade could seriously affect your blood pressure.

- are taking ritonavir or indinavir, medicines used to treat human immunodeficiency virus (HIV) infections.
- are over 75 years of age and are taking ketoconazole or itraconazole, anti-fungal medicines.
- have a severe heart or liver problem.
- are having kidney dialysis.
- have recently had a stroke or heart attack.
- have or have had low blood pressure.
- family has a history of degenerative eye diseases (such as retinitis pigmentosa).
- 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).
- 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 Waymade 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 Waymade.

### **Take special care with Vardenafil Waymade if you**

- have heart trouble. It may be risky for you to have sex.
- suffer from irregular heart beat (*cardiac arrhythmia*) or inherited heart diseases affecting your electrocardiogram.
- have a physical condition affecting the shape of the penis. This includes conditions called angulation, Peyronie's disease and cavernosal fibrosis.
- have an illness that can cause erections which won't go away (*priapism*). These include sickle cell disease, multiple myeloma and leukaemia.
- have stomach ulcers (also called *gastric* or *peptic ulcers*).
- have a bleeding disorder (such as *haemophilia*).
- are using any other treatments for erection difficulties, including Vardenafil orodispersible tablets (see section: Other medicines and Vardenafil Waymade).
- experience sudden decrease or loss of vision, stop taking Vardenafil Waymade and contact your doctor immediately.

### **Children and adolescents**

Vardenafil Waymade is not intended for use by children or adolescents under the age of 18.

### **Other medicines and Vardenafil Waymade**

Please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription.

Some medicines may cause problems, especially these:

- nitrates, medicines for angina, or nitric oxide donors, such as amyl nitrite. Taking these medicines with Vardenafil Waymade could seriously affect your blood pressure. Talk to a doctor without taking Vardenafil Waymade.
- medicine for the treatment of arrhythmias, such as quinidine, procainamide, amiodarone or sotalol.

- ritonavir or indinavir, medicines for HIV. Talk to a doctor without taking Vardenafil Waymade.
- 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*).
- Riociguat.

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

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

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

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

Vardenafil Waymade is not for use by women.

### **Driving and using machines**

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

### **Vardenafil Waymade contains Tartrazine (E102) and Sunset Yellow (E110)**

Vardenafil Waymade film-coated tablets contain tartrazine aluminium lake (E102) and sunset yellow FCF aluminium lake (E110), which may cause allergic reactions.

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

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is 10 mg.

Take a Vardenafil Waymade 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 Waymade.

Swallow one tablet with a glass of water.

**Do not take Vardenafil Waymade** with any other forms of vardenafil.

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

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

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

Men who take too much Vardenafil Waymade may experience more side effects or may get severe back pain. If you take more Vardenafil Waymade 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.

##### **Serious side effects**

Partial, sudden, temporary or permanent decrease or loss of vision in one or both eyes has been experienced by patients. Stop taking Vardenafil Waymade and contact your doctor immediately.

Sudden decrease or loss of hearing has been reported.

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

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

- headache

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

- dizziness
- flushing (feeling of warmth and rapid reddening of the face, neck or upper chest)
- blocked or runny nose
- indigestion

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

- swelling of skin and mucous tissue including swollen face, lips or throat
- sleep disorder
- numbness and impaired perception of touch
- sleepiness
- effects on vision, redness of the eye, effects on colour vision, eye pain and discomfort, light sensitivity
- ringing in the ears, vertigo
- fast heart beat or pounding heart
- breathlessness
- stuffy nose
- acid reflux, gastritis (inflammation of the protective lining of the stomach), abdominal pain, diarrhoea, vomiting, feeling sick (*nausea*), dry mouth
- raised levels of liver enzymes in your blood
- rash, reddened skin
- back or muscle pain, increase in blood of a muscle enzyme (*creatine phosphokinase*), muscle stiffness
- prolonged erections
- malaise (feeling unwell)

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

- inflammation of the eyes (*conjunctivitis*)
- allergic reaction
- anxiety
- fainting
- amnesia (memory loss)
- seizure
- increase pressure in the eye (*glaucoma*), lacrimation (flow of tears) increased
- effects on the heart (such as heart attack, altered heart beat or *angina*)
- high or low blood pressure
- nose bleed
- effect on results of blood tests to check liver function
- sensitivity of the skin to sun light
- painful erections
- chest pain
- temporarily decreased blood flow to parts of the brain

**Very rare or not known:** (may affect less than 1 in 10,000 users or frequency cannot be estimated from the available data)

- blood in the urine (*Haematuria*)
- penile bleeding (*Penile Haemorrhage*)
- presence of blood in the semen (*Haematospermia*)
- sudden death
- bleeding in the brain

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.

### **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 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 Waymade**

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.

5 mg, 10 mg and 20 mg (Aluminium-aluminium blister):  
This medicine does not require any special storage conditions.

5 mg and 10 mg (Aluminium-PVC and aluminium-PVC/PVdC blister)  
This medicine does not require any special storage conditions.

20 mg (Aluminium-PVC and aluminium-PVC/PVdC blister)  
Do not store above 30°C.

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 to protect the environment.

## 6. Contents of the pack and other information

### What Vardenafil Waymade contains

- The active substance is vardenafil.  
Each tablet contains 5 mg, 10 mg or 20 mg of vardenafil (as hydrochloride trihydrate).
- The other ingredients of the tablets are:  
**Tablet core:** Cellulose, microcrystalline, hydroxypropylcellulose, crospovidone Type B, silica colloidal anhydrous, magnesium stearate  
**Film-coat:** Opadry beige 03F570025

Composition of Opadry beige 03F570025: Hypromellose (E464), titanium dioxide (E171), macrogol (E1521), iron oxide yellow (E172), tartrazine aluminium lake (E102), sunset yellow FCF aluminium lake (E110), iron oxide red (E172).

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

Vardenafil Waymade 5 mg is a light orange to orange, film-coated round tablet debossed with 'L' on one side and '05' on the other side.

Vardenafil Waymade 10 mg is a light orange to orange, film-coated round tablet debossed with '480' on one side and plain on the other side.

Vardenafil Waymade 20 mg is a light orange to orange, film-coated round tablet debossed with '481' on one side and plain on the other side.

Vardenafil Waymade 5 mg, 10 mg and 20 mg is available in blister packs of 4 tablets.  
Vardenafil Waymade 20 mg is also available in blister packs of 8 tablets.  
Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder

Sovereign Medical, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, United Kingdom

#### Manufacturer

Waymade PLC, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, United Kingdom

**This leaflet was last revised in September 2024**

<b>PL 06464/3104</b>	Vardenafil Waymade 5 mg film-coated tablets
<b>PL 06464/3105</b>	Vardenafil Waymade 10 mg film-coated tablets
<b>PL 06464/3106</b>	Vardenafil Waymade 20 mg film-coated tablets

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