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PACKAGE LEAFLET: INFORMATION FOR THE USER

P3373T

Vardenafil Crescent 5mg, 10mg and 20mg Film-coated tablets

vardenafil hydrochloride trihydrate

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

1. What Vardenafil Tablets are and what they are used for

The full name of your medicine is Vardenafil Crescent 5mg, 10mg and 20mg film-coated tablets, but within the leaflet it will be referred to as Vardenafil Tablets.

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

2. What you need to know before you take Vardenafil Tablets

DO NOT take Vardenafil Tablets

- 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 Tablets.
- 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 Tablets could seriously affect your blood pressure.
- If you are taking ritonavir or indinavir, medicines used to treat human immunodeficiency virus (HIV) infections.
- 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 Tablets 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 Tablets.

Take special care with Vardenafil Tablets

- 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 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, including vardenafil orodispersible tablets (see section: Other medicines and Vardenafil Tablets).
- Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, have been reported in association with vardenafil treatment. Stop using Vardenafil Tablets 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 Tablets, stop taking Vardenafil Tablets and contact your doctor IMMEDIATELY.

Children and adolescents

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

Other medicines and Vardenafil Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 Tablets could seriously affect your blood pressure.
- Medicine for the treatment of arrhythmias, such as quinidine, procainamide, amiodarone or sotalol.
- Ritonavir or indinavir, medicines for HIV.
- 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 Tablets combined with any other treatment for erectile dysfunction, including orodispersible tablets.

Vardenafil Tablets with food, drink and alcohol

- You can take Vardenafil Tablets 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 Tablets. It can interfere with the usual effect of the medicine.
- Alcoholic drink can make erection difficulties worse.

Pregnancy and breast-feeding

Vardenafil Tablets are not for use by women.

Driving and using machines

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

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150mm
Front Side



Product:	Vardenafil 5mg, 10mg & 20mg film-coated tablets
Item Code:	P3373T
Size:	150 x 400 mm
Min. Point size:	8pt
O. Artwork:	23/04/25
Proof No.	1
Amendment Date	

Colours Used	
	Process Black
	Keyline - Does not print

400mm

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Vardenafil Tablets contain tartrazine and sunset yellow FCF

Vardenafil Tablets contain tartrazine aluminium lake (E102) and sunset yellow FCF aluminium lake (E110), which may cause allergic reactions.

3. How to take Vardenafil Tablets

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 10mg.

Take a Vardenafil Tablets 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 Tablets.

Swallow one tablet with a glass of water. Do not take Vardenafil Tablets with any other forms of vardenafil.

DO NOT take Vardenafil Tablets more than once a day.

Tell your doctor if you think Vardenafil Tablets are 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 take more Vardenafil Tablets than you should

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

If you have 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.

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. Stop taking Vardenafil Tablets and contact your doctor IMMEDIATELY.

Sudden decrease or loss of hearing has been reported.

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.

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
- 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, 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

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

- Inflammation of the eyes (conjunctivitis)
- Allergic reaction
- Anxiety
- Fainting
- Amnesia

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- Seizure
- Increased pressure in the eye (glaucoma), lacrimation 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
- 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, 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 Website: 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 Tablets

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 after “EXP”. The expiry date refers to the last day of that month.

5mg and 10mg: This medicinal product does not require any special storage conditions.

20mg: 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 protect the environment.

6. Contents of the pack and other information

What Vardenafil Tablets contain

- The active substance is vardenafil. Each tablet of Vardenafil Tablets contains 5mg, 10mg or 20mg of vardenafil (as hydrochloride trihydrate).
- The other ingredients are:
Tablet core: microcrystalline cellulose; crospovidone Type B; colloidal anhydrous silica; hydroxypropylcellulose; magnesium stearate
Film-coating: 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 Tablets look like and contents of the pack

Vardenafil 5mg Tablets are light orange to orange, film-coated round tablets debossed with “L” on one side and “05” on the other side. Approximately 5.35 mm in diameter.

Vardenafil 10mg Tablets are light orange to orange, film-coated round tablets debossed with “480” on one side and plain on the other side. Approximately 6.10 mm in diameter.

Vardenafil 20mg Tablets are light orange to orange, film-coated round tablets debossed with “481” on one side and plain on the other side. Approximately 8.10 mm in diameter.

Vardenafil Tablets are available in blister pack of Aluminium foil and transparent PVC/PVdC film containing 4 or 8 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer



Crescent Pharma Ltd., Key House, Sarum Hill, Basingstoke, RG21 8SR, UK.

This leaflet was last revised in April 2025.

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150mm
Back Side

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