

VI.2 Elements for a Public Summary

The following public summary applies to all products in this RMP.

VI.2.1 Overview of disease epidemiology

Impotence, also known as erectile dysfunction, is the inability to have and maintain an erection. Impotence is a very common condition, particularly in older men. It is estimated that half of all men between the ages of 40 and 70 will experience impotence to some degree, with approximately 5-20% of men having moderate to severe impotence.

Erections are caused by the brain sending signals to the nerves in the penis when a man becomes sexually aroused. The nerves increase blood flow to the penis which causes the penis tissue to expand and harden. Impotence occurs due to interference with this process. Physical causes include:

- narrowing of the blood vessels going to the penis, commonly associated with high blood pressure, high cholesterol or diabetes
- conditions affecting hormone levels
- conditions affecting the nervous system (comprising the brain, nerves and spinal cord)
- conditions affecting the physical structure of the penis

In addition, reduction of sexual desire (libido), in particular due to psychological and emotional conditions such as anxiety, depression, relationship problems and past sexual problems lead to impotence because a reduced libido makes it more difficult for the brain to trigger an erection.

Impotence can also be a side-effect of using certain medicines. Medications which may cause impotence include treatments for high blood pressure, fibrates used to lower cholesterol levels, medications used to treat depression and mental health conditions such as schizophrenia, steroids, treatments for stomach ulcers, epilepsy, and allergic health conditions, medications which suppress male sex hormones and some chemotherapy drugs.¹

VI.2.2 Summary of treatment benefits

Vardenafil is a member of a class of medicines called phosphodiesterase type 5 (PDE5) inhibitors. Other products in this class include sildenafil (Viagra) and tadalafil (Cialis). These are commonly prescribed in patients where treatment of a medical condition causing impotence is not possible or does not provide a resolution. In most patients, vardenafil can cause erections within a period of 25 minutes to 5 hours after taking it. Other treatments for impotence include vacuum pumps, alprostadil and semi-rigid or inflatable penis implants. Although these methods can have a higher success rate in producing erections, vardenafil can be taken discretely in advance of sex, and does not require surgery or potentially intrusive methods of administration.

In clinical trials vardenafil was given to over 17,000 men with impotence aged 18 - 89 years with over 2,500 patients treated for six months or longer. Across the trials, treatment with vardenafil resulted in an improvement in ability to attain an erection. In a survey conducted amongst users, most patients experienced improved erections after the first (73.6%) or second (88.5%) tablet. Sexual attempts were successful with respect to penetration (94.9%) and maintenance of erection (87.7%). Side effects were very rare (1.3% of patients).²

VI.2.3 Unknowns relating to treatment benefits

The use of vardenafil has not been studied in patients undergoing kidney dialysis or those with severe reduction of liver function, low blood pressure, recent stroke or heart attack, unstable angina or a personal or family history of hereditary eye diseases. Vardenafil should not be taken by such patients.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Allergy to vardenafil (Hypersensitivity)	Allergic reactions have been reported with vardenafil and similar products. These reactions can progress to a life-threatening side effect, even after the first administration.	As the reaction is unpredictable the reaction cannot be prevented other than by avoidance in patients with known allergy. Vardenafil should be stopped and suitable treatment for any reactions initiated, if required.
Low blood pressure (Hypotension / Increased hypotensive effect)	Vardenafil works by helping to increase blood flow into the penis during sexual stimulation. This helps the patient to achieve and maintain an erection. To do this, vardenafil causes the patient's blood vessels to widen. This could cause a mild and brief decrease in blood pressure. There is a potential risk to patients with existing low blood pressure of the blood pressure dropping further and causing side effects related to low blood pressure, such as unsteadiness, dizziness or fainting. ³	The patient should speak to their doctor if they were taking nitrates before taking vardenafil. Monitoring of the patient's blood pressure for early signs of any changes may be appropriate.
Erection that will not go away (Prolonged erection / Priapism)	Vardenafil works to help patients obtain an erection. If used in combination with conditions that can increase the risk of prolonged erection, or in patients with deformities of the penis, the effect could be additive when using vardenafil. This can lead to prolonged and painful erections.	The patient's doctor should speak to their patient regarding the risk if they have any blood cell problems, conditions that increase the risk of a prolonged erection, or deformities of the penis.

<p>Effects on the rhythm and activity of the heart (Effects on QT-interval and cardiac rhythm (arrhythmias))</p>	<p>Vardenafil can cause alterations to the heart beat such as a fast heart beat or pounding of the heart. These can lead to complications in patients who have existing heart diseases.</p>	<p>Patients with existing heart conditions, particularly those who are taking medications for abnormal heart rhythms (such as quinidine, amiodarone and sotalol), should not take the drug.</p>
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Summary EU-Risk Management Plan

Risk	What is known	Preventability
<p>Taking vardenafil with certain drugs and foodstuffs that can affect the way vardenafil is broken down in the body (Overdose due to concomitant use of CYP3A4 inhibitors))</p>	<p>Some medications interfere with the compounds produced by the liver that are responsible for breaking down vardenafil for removal from the body. Patients taking such medications should not take vardenafil at the same time as they are at risk of high levels of the drug in their body, equivalent to taking an overdose. Similarly, a component of grapefruit juice has the same effect.</p>	<p>The patient should speak to their doctor if they are taking antifungal (e.g. itraconazole and ketoconazole) and anti-retroviral medications (e.g. medications for HIV, including ritonavir and indinavir) before taking vardenafil. In addition patients should avoid eating grapefruit or drinking grapefruit juice.</p>

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
<p>Effects on your eyes (Effects on vision [e.g. visual defects and Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION)])</p>	<p>Sudden decrease and loss of vision have been reported with vardenafil and similar products. These reactions can progress to have a negative effect on the patient quality of life and health. The patient should be warned that if their vision is affected they should not drive.</p>
<p>Blurring or distortion of vision due to fluid leakage in the eye (Central serous retinopathy)</p>	<p>A very small number of patients receiving vardenafil and other medicines in the same drug family have developed a condition known as central serous retinopathy. This condition affects part of the eye called the retina and is associated with blurred or distorted vision due to fluid leakage in the eye.</p>
<p>Seizures (Epilepsy / seizure / convulsion)</p>	<p>There have been, in rare instances, reports of seizures in patients receiving therapy with vardenafil and other related products. These have been observed in otherwise healthy patients with no prior history of epilepsy as well as in patients with epilepsy. It is currently not known why these seizures occur. ⁴</p>
<p>Sudden episodes of memory loss (Transient global amnesia)</p>	<p>Rare reports have been received of patients experiencing sudden temporary memory loss in association with use of vardenafil and similar products. The relationship between this memory loss and vardenafil is not understood at this time.</p>

Sudden decrease or loss of hearing (Sudden deafness)	Sudden decrease or loss of hearing has been reported as a possible side effect of vardenafil and other related products. The number of known instances is low and currently the frequency of this occurring in the general population cannot be established from the available data.
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Missing information

None

VI.2.5 Summary of risk minimisation measures by safety concern

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All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The SmPC and PL for vardenafil can be found on the webpage of the National Competent Authority. The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post authorisation development plan was proposed.

VI.2.7 Summary of changes to the Risk Management Plan over time

Major changes to the Risk Management Plan over time.

Version	Date	Safety Concerns	Comment
Not applicable	-	-	-