VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

This product 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.

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

Erectile dysfunction (ED) has been reported to affect 152 million men worldwide. The risk of ED increases progressively with age and is associated with a number of other conditions. A recent review has concluded that the prevalence of ED of all degrees is 52% in men 40 to 70 years old. The prevalence of ED is expected to continue to increase with an estimated 328 million men worldwide affected by year 2025.

VI.2.2 Summary of treatment benefits

This product contains vardenafil, a member of a class of medicines called phosphodiesterase type 5 (PDE5) 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 is a potent and highly selective PDE5 inhibitor developed as an oral therapy for ED. It is effective and generally well tolerated in men with mild to severe ED of varying aetiology, as well as in men with ED associated with diabetes mellitus or ED after radical prostatectomy. Vardenafil patients report a high degree of satisfaction due to a high quality of response. Vardenafil acts rapidly; works the first time and in most patients performs consistently over time and offers first-line therapy with favourable safety and tolerability. Vardenafil has been well-tolerated in clinical trials. The adverse events (AEs) noted most often with its use were expected based on the pharmacology of PDE5 inhibitors. The most common adverse events were headache, flushing, rhinitis and dyspepsia, which were mild-to-moderate in severity and they generally attenuated with continued use.

VI.2.3 Unknowns relating to treatment benefits

This product is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Allergic reactions **Hypersensitivity**	These medications may cause allergic reactions as all medicines can.	Yes, by monitoring for early symptoms and avoiding the drugs you are already known to be allergic to. By telling the doctor if allergic reactions have been experienced previously. By not taking this medicine if symptoms such as rash, itching, swollen face or lips and shortness of breath occurred with vardenafil or any other ingredients of this medicine.
Low blood pressure **Decrease in blood pressure**	Vardenafil has vasodilator properties, resulting in mild and transient decrease in blood pressure. Concomitant use of some drugs lowering blood pressure may contribute to	Yes, by telling the doctor if you have or have had low blood pressure. By telling your doctor if any other medicines that could seriously affect your blood

Risk	What is known	Preventability
	decrease in blood pressure. Vardenafil and alpha-blocker as well can cause lowering of blood pressure, especially postural hypotension and syncope. PDE5 inhibitors, such as vardenafil, have been shown to potentiate the hypotensive effects of nitrates, co-administration with nitric oxide donors or nitrates in any form is not allowed.	pressure are taken. Treatment with this product can be affected by other medicines such as alpha-blockers, a type of medicine used to treat high blood pressure and enlargement of the prostate and if taking any medicines containing nitrates, such as glycerol trinitrate for angina, or nitric oxide donors, such as amyl nitrite.
Effects on electrocardiogram and the heart rhythm **Effects on QT-interval and cardiac rhythm**	Single oral doses of vardenafil have been shown to have effect on heart rhythm (changes in electrocardiogram, e.g. prolong the QTc interval). Medicinal products that may prolong QTc interval, including vardenafil, are best avoided in patients with relevant risk factors.	Yes, by telling the doctor if you have severe heart problems or you had a stroke or heart attack recently. Special care should be taken in case of heart problem. It may be risky to have sex. Also, if suffering from irregular heart beat (cardiac arrythmia) or inherited heart diseases affecting electrocardiogram special care should be taken.
Prolonged erection	Some illnesses can cause erections which won't go away.	Yes, by taking special care if any illnesses that can cause erections which won't go away are present.
Concomitant use of CYP3A4 inhibitors **Interaction with CYP3A4 inhibitors**	The interaction with certain inhibitors may cause your body to metabolize the medicine slower than intended and increase the levels of vardenafil in your blood. It may result in more severe drop of blood pressure or some other side effects.	Yes, by telling the doctor or pharmacist if taking any other medication. Treatment with this product can be affected by other medicines or even by grapefruit juice.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Loss of vision **Ocular adverse events: NAION**	Vardenafil treatment was associated with a low incidence of adverse events related to vision and eye complaints and most of these were of mild intensity. The ability to drive may be compromised due to effect on the vision. Vardenafil should not be used in patients who have ever had loss of vision because of a problem with blood flow to the nerve in the eye (non-arteritic anterior ischemic optic neuropathy or NAION).
Transient amnesia	Transient amnesia has been reported with use of phosphodiesterase-5 inhibitors, such as vardenafil.
Epilepsy/Seizure/Convulsion	Seizure has been reported with use of phosphodiesterase-5 inhibitors, such as vardenafil.
Eye diseases **Central serous retinopathy**	Vardenafil treatment was associated with a low incidence of adverse events related to vision and eye complaints and most of these were of mild intensity. The ability to drive may be compromised due to effect on the vision. Vardenafil should not be used in patients whose family has a history of degenerative eye diseases (such as retinitis pigmentosa).
Loss of hearing **Sudden deafness**	Sudden decrease or loss of hearing has been reported with use of phosphodiesterase-5 inhibitors, such as vardenafil.

Missing information

Not applicable.

VI.2.5 Summary of risk minimisation measures by safety concern

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 measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for this product can be found at the agency's EPAR page.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

Not applicable. No postauthorisation studies are planned.

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

Not applicable, this is the first Risk management plan.