PUBLIC SUMMARY OF RISK MANAGEMENT PLAN (RMP)

VALINGER 25 MG FILM-COATED TABLETS

ORION CORPORATION

DATE: 21-11-2016, VERSION 1

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Erectile dysfunction (ED) is the inability of a man to develop or maintain an erection during sexual activity. An erection of the penis is the result of blood entering and temporarily remaining in the penis during sexual arousal and requires proper functioning of the brain, hormones, heart, blood vessels, and nerves. As a result, ED can be caused by psychological factors, as well as heart, blood vessel, nervous, and hormonal factors. Erectile dysfunction increases in frequency with increasing age. For example, about 25% of men in their 50s have compared with 45% of men in their 60s. Erectile dysfunction may occur more commonly in men who have heart or blood vessel disease, diabetes, obesity, high blood pressure, nerve damage due to injury or surgery for prostate cancer, or who smoke or drink excessively.

VI.2.2 Summary of treatment benefits

Clinical studies show that at a range of doses from 5 mg to 200 mg, sildenafil was effective in improving the ability to achieve and maintain erections sufficient for sexual intercourse and was most effective in the range of 25 mg to 200 mg.

Sildenafil is effective in treating erectile dysfunction from all common causes, including diabetes and spinal cord injury. Diabetic patients and patients who have had their prostate removed did not obtain as good a response to sildenafil (ED) as patients who did not have these conditions.

VI.2.3 Unknowns relating to treatment benefits

In the clinical program the majority of patients were white. There is no reason to believe that members of other racial groups are affected differently. The following sub-groups of patients were not studied in sildenafil (ED) clinical trials: patients with severe liver disease, low blood pressure, recent history of stroke or heart attack, and certain inherited conditions of the eye. Another form of sildenafil is used for the treatment of high blood pressure in the lungs. However, sildenafil (ED) has not been studied for this use.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Interaction with drugs containing nitrates (nitrate interaction)	A patient who is taking a drug that contains nitrates, such as glyceryl trinitrate and isosorbide dinitrate, could have a serious drop in blood pressure after taking sildenafil.	Sildenafil should not be used in men who are using nitrates.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Interruption of the blood supply to the main nerve of the eye (non-arteritic anterior ischaemic optic neuropathy [NAION])	Sildenafil should not be used in men who have loss of vision in one eye because of the risk of problem with blood flow to the nerve in the eye. In case of sudden visual defect, patient should stop taking sildenafil and consult a physician immediately
Bleeding within the eye (eye haemorrhage)	There is a risk that patients taking sildenafil could develop visual changes caused by bleeding within the eye. In case of sudden visual defect, patient should stop taking sildenafil and consult a physician immediately.
Sudden hearing loss	There is a risk that patients taking sildenafil could develop a sudden hearing loss. In case of sudden hearing loss, patient should stop taking sildenafil and consult a physician immediately.

Missing information

Risk	What is known
Severely impaired liver function (severe hepatic impairment)	Sildenafil was not studied in patients who have severely impaired liver function and should not be used in these patients.

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 medicinal product can be found in the national authority's web page.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan (if applicable)

Not applicable.

VI.2.7 Summary of changes to the risk management plan over time

Not applicable.