PUBLIC SUMMARY OF RISK MANAGEMENT PLAN (RMP)

ALFUZOSIN HYDROCHLORIDE ORION 10 MG PROLONGED-RELEASE TABLETS

ORION CORPORATION

DATE: 25-09-2015, VERSION 1.0

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Active ingredient of this medicinal product, alfuzosin, belongs to a group of medicines called alpha1-blockers. It is used to treat urinary symptoms caused by enlargement of the prostate gland in men.

Prostate gland enlargement, also called benign prostatic hyperplasia (BPH), is a common condition as men get older. It is very common among older men, affecting about 60% of men over age 60 and 80% of men over age 80. Symptoms often start after age 50.

Prostate gland enlargement is not a cancerous or precancerous condition. It rarely causes serious complications. However, untreated prostate gland enlargement can block the flow of urine out of the bladder and cause bladder, urinary tract or kidney problems. Bothersome urinary symptoms include difficulty urinating (hesitation, dribbling, weak stream, and incomplete bladder emptying), painful urination, and increased urinary frequency and urgency.

The severity of symptoms in people who have prostate gland enlargement varies, but symptoms tend to gradually worsen over time. The size of prostate doesn't necessarily mean symptoms will be worse. Some men with only slightly enlarged prostates can have significant symptoms, while other men with very enlarged prostates can have only minor urinary symptoms.

Treatment options include medications and surgery.

VI.2.2 Summary of treatment benefits

Alfuzosin belongs to a group of medicines known as alpha-blockers. It works by blocking the action of certain nerve impulses. This blocking action is useful in controlling the symptoms of prostate gland enlargement. Alfuzosin helps to relax the muscles in the prostate and the opening of the bladder. This may help to increase the flow of urine out of the bladder. However, alfuzosin will not shrink the prostate. The prostate may continue to get larger.

VI.2.3 Unknowns relating to treatment benefits

Efficacy of alfuzosin has not been demonstrated in children aged 2 to 16 years. Therefore, alfuzosin is not indicated for use in paediatric population.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
Too low blood pressure, including drop in blood pressure upon sitting or standing up quickly and concomitant use of other medicines belonging to the same group and other blood pressure lowering medicines (Hypotension, including orthostatic hypotension and concomitant use with alpha-1-blockers or other blood pressure lowering medicines)	Alfuzosin relaxes muscles around blood vessels and can thus lower blood pressure. When using alfuzosin some patients may experience dizziness or light-headedness, which may be caused by too low blood pressure especially upon sitting or standing up quickly. In some patients drop in blood pressure in sitting or standing position with or without symptoms (dizziness, fatigue, sweating) may develop within a few hours following administration. These effects are transient, occur in the beginning of treatment and do not usually prevent the continuation of treatment. Pronounced drop in blood pressure has been reported in post-marketing surveillance in patients with pre-existing risk factors (such as underlying cardiac diseases and/or concomitant treatment with anti-hypertensive medication).	Patients should avoid sitting or standing up quickly especially in the beginning of the treatment. In case of symptoms of too low blood pressure patient should lay on the floor with feet up. It is recommended to avoid driving or operating machinery in the beginning of the treatment as dizziness or weakness may occur. Concomitant administration with other blood pressure lowering medicines should be discussed and agreed with doctor. Other medicines belonging to the same group as alfuzosin should not be used concomitantly.

Use in patients with impaired liver function (Administration in patients with hepatic insufficiency)	In patients with liver impairment alfuzosin stays longer time in body and concentration in blood may become too high increasing risks for side effects.	Alfuzosin 10 mg prolonged release tablets must not be used in patients with impaired liver function and alfuzosin 2.5 mg must not be used if liver function is severely impaired.

Important potential risks

Risk	**What is known (Including reason why it is considered a potential risk)**
Disorders of blood flow in brains and heart muscle (Cerebral and cardiovascular ischemic disorders)	Alfuzosin-induced hypotension may worsen existing blood flow related problems in heart muscle and brains. E.g. symptoms of angina (severe chest pain) may reappear or get worse.
Changes in electrical activity of the heart (QT prolongation)	Changes in electrical activity of the heart (QT prolongation) may occur during alfuzosin therapy and can lead to severe heart rhythm disturbances. Special caution should be administered in patients with risk for prolonged QT interval due to genetic background or medication or in patients who have previously had prolonged QT interval.
Possible complication during cataract surgery (Intraoperative Floppy Iris Syndrome)	The 'Intraoperative Floppy Iris Syndrome' (IFIS, a variant of small pupil syndrome) has been observed during cataract surgery in some patients on or previously treated with tamsulosin. Isolated reports have also been received with other medicines belonging to the same medicinal group (alpha-1 blockers such as alfuzosin) and the possibility of a class effect cannot be excluded. As IFIS may lead to increased procedural complications during the cataract operation, current or past use of alfuzosin should be made known to the eye surgeon well before the operation.
Use in older patients (Administration in elderly patients)	The risk of developing hypotension and related adverse reactions may be greater in elderly patients.

Missing information

Risk	What is known
Use in patients with severely impaired kidney function (Administration in patients with severe renal impairment)	There are no clinical safety data available in patients with severely impaired kidney function.

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 xx 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

Not applicable.

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

Not applicable.