VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Active ingredient of this medicinal product, tamsulosin, belongs to a group of medicines called alpha$_1$-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

Tamsulosin 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. Tamsulosin 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, tamsulosin will not shrink the prostate. The prostate may continue to get larger.

VI.2.3 Unknowns relating to treatment benefits

The safety and efficacy of tamsulosin in children aged under 18 years have not been established.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
Drop in blood pressure upon standing up quickly from sitting or lying down (orthostatic hypotension)	Tamsulosin relaxes muscles around blood vessels and can thus lower blood pressure. When using tamsulosin some patients may experience dizziness or light-headedness, which may be caused by too low blood pressure especially upon standing up quickly from sitting or lying down. In rare cases sudden drop in blood pressure	Tamsulosin should not be used if the patient has previously suffered from orthostatic hypotension. At the first signs of orthostatic hypotension (dizziness, weakness), the patient should sit or lie down until the symptoms have disappeared. Concomitant administration of

Risk	What is known	Preventability
	can lead to fainting (syncope).	medicines (alpha$_1$-blockers) belonging to the similar class as tamsulosin can increase the risk orthostatic hypotension.
Possible complication during cataract or glaucoma surgery (Intraoperative Floppy Iris Syndrome)	The 'Intraoperative Floppy Iris Syndrome' (IFIS, a variant of small pupil syndrome) has been observed during cataract or glaucoma surgery in some patients on or previously treated with tamsulosin. IFIS may lead to increased procedural complications during the cataract operation.	Current or past use of tamsulosin should be made known to the eye surgeon well before the operation in order to ensure that appropriate measures will be in place to manage the IFIS during surgery. The initiation of therapy with tamsulosin hydrochloride in patients for whom cataract or glaucoma surgery is scheduled is not recommended.
Angioedema	Angioedema is usually suddenly appearing swelling of the deeper layers of the skin, caused by a build-up of fluid. The symptoms of angioedema can affect any part of the body, but swelling usually affects the eyes, lips, genitals, hands or feet. In severe cases, the inside lining of the throat and bowel can be affected. Angioedema has been rarely reported after the use of tamsulosin.	Patients who have earlier had drug-induced angioedema, should not take tamsulosin. If symptoms of angioedema appear, treatment should be discontinued immediately, the patient should be monitored until disappearance of the oedema, and tamsulosin should not be used in the future.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Concomitant administration with medicines that significantly inhibit break down of tamsulosin in the liver (Concomitant administration with strong CYP3A4 inhibitors)	Concomitant administration of certain medicines such as orally administered ketoconazole can increase levels of tamsulosin in blood by inhibiting its breakdown in the liver. The risk is higher in patients who have abnormal function of certain liver enzymes (poor CYP2D6 metabolizers).

Missing information

Risk	What is known
Administration in pediatric patients	The safety and efficacy of tamsulosin in children aged under 18 years have not been established. Interaction studies have only been performed in adults.

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.