Core Safety Profile

Active substance:	**Tamsulosin**
Pharmaceutical form(s)/strength:	**Modified release capsules, hard, 0.4mg**
P-RMS:	**NL/H/PSUR/0014/001**
Date of FAR:	**25.03.2010**

1. NAME OF THE MEDICINAL PRODUCT

/…/ 0,4, 0.4 mg, modified release capsules, hard

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains as active ingredient tamsulosin hydrochloride 0.4 mg.

Excipient(s):
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Modified release capsule, hard

Orange/olive-green coded 0.4 and logo and 701

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH).

4.2 Posology and method of administration

Oral use

One capsule daily, to be taken after breakfast or the first meal of the day.

The capsule must be swallowed whole and must not be crunched or chewed, as this interferes with the modified release of the active ingredient.

No dose adjustment is warranted in renal impairment. No dose adjustment is warranted in patients with mild to moderate hepatic insufficiency (see also 4.3 Contraindications).

There is no relevant indication for use of /…/ in children.

4.3 Contraindications

Hypersensitivity to tamsulosin hydrochloride, including drug-induced angioedema or to any of the excipients.

A history of orthostatic hypotension.

Severe hepatic insufficiency.

4.4 Special warnings and precautions for use

As with other α_1-adrenoceptors antagonists, a reduction in blood pressure can occur in individual cases during treatment with /…/ 0,4, as a result of which, rarely, syncope can occur. At the first signs of orthostatic hypotension (dizziness, weakness), the patient should sit or lie down until the symptoms have disappeared.

Before therapy with /…/ 0,4 is initiated, the patient should be examined in order to exclude the presence of other conditions, which can cause the same symptoms as benign prostatic hyperplasia. Digital rectal examination and, when necessary, determination of prostate specific antigen (PSA) should be performed before treatment and at regular intervals afterwards.

The treatment of patients with severe renal impairment (creatinine clearance of < 10 ml/min) should be approached with caution, as these patients have not been studied.

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. IFIS may lead to increased procedural complications during the operation. The initiation of therapy with tamsulosin in patients for whom cataract surgery is scheduled is not recommended.

Discontinuing tamsulosin 1-2 weeks prior to cataract surgery is anecdotally considered helpful, but the benefit and duration of stopping of therapy prior to cataract sugery has not yet been established.

During pre-operative assessment, cataract surgeons and ophthalmic teams should consider whether patients scheduled for cataract surgery are being or have been treated with tamsulosin in order to ensure that appropriate measures will be in place to manage the IFIS during surgery.

4.5 Interaction with other medicinal products and other forms of interaction

Interaction studies have only been performed in adults.

No interactions have been seen when tamsulosin hydrochloride was given concomitantly with either atenolol, enalapril~~, nifedipine~~ or theophylline. Concomitant cimetidine brings about a rise in plasma levels of tamsulosin, whereas furosemide a fall, but as levels remain within the normal range posology need not be adjusted.

In vitro, neither diazepam nor propranolol, trichlormethiazide, chlormadinon, amitriptyline, diclofenac, glibenclamide, simvastatin and warfarin change the free fraction of tamsulosin in human plasma. Neither does tamsulosin change the free fractions of diazepam, propranolol, trichlormethiazide and chlormadinon.

No interactions at the level of hepatic metabolism have been seen during in vitro studies with liver microsomal fractions (representative of the cytochrome P_{450}-linked drug metabolizing enzyme system), involving amitriptyline, salbutamol, glibenclamide and finasteride. Diclofenac and warfarin, however, may increase the elimination rate of tamsulosin.

Concurrent administration of other α_1-adrenoceptor antagonists could lead to hypotensive effects.

4.6 Pregnancy and lactation

Not applicable as /…/ 0,4 is intended for male patients only.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, patients should be aware of the fact that dizziness can occur.

4.8 Undesirable effects

System Organ Class	Common >1/100, <1/10	Uncommon >1/1000, 1/100	Rare >1/10,000,< 1/1000	Very rare <1/10,000
Nervous system disorders	dizziness (1.3%)	headache	syncope	
Cardiac disorders		palpitations		
Vascular disorders		~~postural~~ orthostatic hypotension		
Respiratory, thoracic and mediastinal disorders		rhinitis		
Gastrointestinal disorders		constipation, diarrhoea, nausea, vomiting		
Skin and subcutaneous tissue disorders		rash, pruritus, urticaria	angioedema	Stevens-Johnson syndrome
Reproductive system and breast disorders	ejaculation disorders	~~abnormal ejaculation disorders~~		priapism
General disorders and administration site conditions		asthenia		

During cataract surgery a small pupil situation, known as Intraoperative Floppy Iris Syndrome (IFIS), has been associated with therapy of tamsulosin during post-marketing surveillance (see also section 4.4).

Post-marketing experience: In addition to the adverse events listed above, atrial fibrillation, arrhythmia, tachycardia and dyspnoea have been reported in association with tamsulosin use. Because these spontaneously reported events are from the worldwide post marketing experience, the frequency of events and the role of tamsulosin in their causation cannot be reliably determined.

4.9 Overdose

Acute overdose with 5 mg tamsulosin hydrochloride has been reported. Acute hypotension (systolic blood pressure 70 mm Hg), vomiting and diarrhoea were observed, which were treated with fluid replacement and the patient could be discharged the same day.

In case of acute hypotension occurring after overdosage cardiovascular support should be given. Blood pressure can be restored and heart rate brought back to normal by lying the patient down. If this does not help then volume expanders and, when necessary, vasopressors could be employed. Renal function should be monitored and general supportive measures applied. Dialysis is unlikely to be of help as tamsulosin is very highly bound to plasma proteins.

Measures, such as emesis, can be taken to impede absorption. When large quantities are involved, gastric lavage can be applied and activated charcoal and an osmotic laxative, such as sodium sulphate, can be administered.