

Abbreviated prescribing information of Harnal OCAS

Abbreviated prescribing information of Harnal OCAS® 0.4 mg Tablets

Version: 003

Composition:

Tamsulosin HCl.

Indications:

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

Dosage:

1 tab daily, can be taken independently of food.

Administration:

Swallow whole, do not chew/crunch.

Contraindications:

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

Special warnings and special precaution for use:

As with other α 1-adrenoceptor antagonists, a reduction in blood pressure can occur in individual cases during treatment with Harnal OCAS® 0.4 mg Tablets, 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 Harnal OCAS® 0.4 mg Tablets 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.

Treatment of patients with a history of orthostatic hypotension should be approached with caution.

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 treatment of patients with severe hepatic dysfunction should be approached with caution.

The 'Intraoperative Floppy Iris Syndrome' (IFIS, a variant of small pupil syndrome) has been observed during cataract and glaucoma surgery in some patients on or previously treated with tamsulosin hydrochloride. IFIS may increase the risk of eye complications during and after the operation. Discontinuing tamsulosin hydrochloride 1-2 weeks prior to cataract or glaucoma surgery is anecdotally considered helpful, but the benefit of treatment discontinuation has not been established. IFIS has also been reported in patients who had discontinued tamsulosin for a longer period prior to the surgery.

The initiation of therapy with tamsulosin hydrochloride in patients for whom cataract or glaucoma surgery is scheduled is not recommended. During pre-operative assessment, surgeons and ophthalmic teams should consider whether patients scheduled for cataract or glaucoma 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.

Tamsulosin hydrochloride should not be given in combination with strong inhibitors of CYP3A4 in patients with poor metaboliser CYP2D6 phenotype. Tamsulosin hydrochloride should be used with caution in combination with strong and moderate inhibitors of CYP3A4.

Cases of allergic reaction to tamsulosin in patients with a past history of sulfonamide allergy have been reported. If a patient reports a previously experienced sulfa allergy, caution is warranted when administering tamsulosin hydrochloride.

Undesirable effects:

Common (>1%, <10%), Uncommon (>0.1%, <1%), Rare (>0.01%, <0.1%), Very rare (<0.01%), Not known (cannot be estimated from the available data).

Cardiac disorder: Uncommon: Palpitations.

Eye disorders: Not known: Vision blurred*, visual impairment*.

Gastrointestinal disorders: Uncommon: Constipation, diarrhoea, nausea, vomiting. **Not known:** Dry mouth*.

General disorders and administration site conditions: Uncommon: Asthenia.

Nervous systems disorders: Common: Dizziness (1.3%). **Uncommon:** Headache. **Rare:** Syncope.

Reproductive system and breast disorders: Common: Ejaculation disorders including retrograde ejaculation and ejaculation failure. **Very rare:** Priapism.

Respiratory, thoracic and mediastinal disorders : Uncommon: Rhinitis. **Not known:** Epistaxis*.

Skin and subcutaneous tissue disorders : Uncommon: Rash, pruritus, urticaria. **Rare:** Angioedema. **Very rare:** Stevens-Johnson syndrome. **Not known:** Erythema multiforme*, dermatitis exfoliative*.

Vascular disorders: Uncommon: Orthostatic hypotension.

*Observed post-marketing.

During cataract and glaucoma surgery a small pupil situation, known as Intraoperative Floppy Iris Syndrome (IFIS), has been reported.

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.

Full prescribing information is available upon request.