### 1. NAME OF THE MEDICINAL PRODUCT
OMNIC OCAS®, 0.4 mg prolonged release tablets, film-coated.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each prolonged release film-coated tablet contains 0.4 mg tamsulosin hydrochloride.

Excipients:
For a full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM
Film-coated, prolonged release tablet (Oral Controlled Absorption System, OCAS).
OMNIC OCAS tablets are round, bi-convex, yellow, film-coated.

### 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 tablet daily.
OMNIC OCAS can be taken independently of food.
The tablet must be swallowed whole and not be crunched or chewed as this interferes with the prolonged release of the active substance.
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).
Paediatric population
There is no relevant indication for use of OMNIC OCAS in children.
The safety and efficacy of tamsulosin in children <18 years have not been established. Currently available data are described in section 5.1

#### 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 α1-adrenoceptor antagonists, a reduction in blood pressure can occur in individual cases during treatment with OMNIC OCAS, 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 OMNIC OCAS 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 hydrochloride. IFIS may increase the risk of eye complications during and after the operation. Discontinuing tamsulosin hydrochloride 1-2 weeks prior to cataract 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 cataract surgery.

The initiation of therapy with tamsulosin hydrochloride in patients for whom cataract surgery is sched-
patients with poor metaboliser CYP2D6 phenotype.
Tamsulosin hydrochloride should be used with caution in combination with strong and moderate inhibitors of CYP3A4.
Concomitant administration of tamsulosin hydrochloride with paroxetine, a strong inhibitor of CYP2D6, resulted in a $C_{\text{max}}$ and AUC of tamsulosin that had increased by a factor of 1.3 and 1.6, respectively, but these increases are not considered clinically relevant.
Concurrent administration of other α1-adrenoceptor antagonists could lead to hypotensive effects.

4.6 Pregnancy and lactation
Not applicable, as OMNIC OCAS 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
See Table.
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

Symptoms
Overdosage with tamsulosin hydrochloride can potentially result in severe hypotensive effects. Severe hypotensive effects have been observed at different levels of overdosing.
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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: α₁-adrenoceptor antagonists.

ATC code: G04C A02. Preparations for the exclusive treatment of prostatic disease.

**Mechanism of action**

Tamsulosin binds selectively and competitively to the postsynaptic α₁-adrenoceptors, in particular to subtypes α₁A and α₁D. It brings about relaxation of prostatic and urethral smooth muscle.

**Pharmacodynamic effects**

OMNIC OCAS increases the maximum urinary flow rate. It relieves obstruction by relaxing smooth muscle in prostate and urethra thereby improving voiding symptoms. It also improves the storage symptoms in which bladder instability plays an important role. These effects on storage and voiding symptoms are maintained during long-term therapy. The need for surgery or catheterisation is significantly delayed.

α₁-adrenoceptor antagonists can reduce blood pressure by lowering peripheral resistance. No reduction in blood pressure of any clinical significance was observed during studies with OMNIC OCAS.

Paediatric population

A double-blind, randomized, placebo-controlled, dose ranging study was performed in children with neuropathic bladder. A total of 161 children (with an age of 2 to 16 years) were randomized and treated at 1 of 3 dose levels of tamsulosin (low [0.001 to 0.0002 mg/kg], medium [0.002 to 0.004 mg/kg], and high [0.004 to 0.008 mg/kg]), or placebo.

The primary endpoint was number of patients who decreased their detrusor leak point pressure (LPP) to <40 cm H₂O based upon two evaluations on the same day. Secondary endpoints were: Actual and percent change from, baseline in detrusor leak point pressure, improvement or stabilization of hydronephrosis and hydroureter and change in urine volumes obtained by catheterisation and number of times wet at time of catheterisation as recorded in catheterisation diaries. No statistically significant difference was found between the placebo group and any of the 3 tamsulosin dose groups for either the primary or secondary end-
In rats, hardly any induction of microsomal liver enzymes was seen to be caused by tamsulosin. *In vitro* results suggest that CYP3A4 and also CYP2D6 are involved in metabolism, with possible minor contributions to tamsulosin hydrochloride metabolism by other CYP isozymes. Inhibition of CYP3A4 and CYP2D6 drug metabolizing enzymes may lead to increased exposure to tamsulosin hydrochloride (see section 4.4 and 4.5).

None of the metabolites are more active than the original compound.

**Elimination**

Tamsulosin and its metabolites are mainly excreted in the urine. The amount excreted as unchanged active substance is estimated to be about 4 - 6% of the dose, administered as OMNIC OCAS.

After a single dose of OMNIC OCAS 0.4 mg and in steady state, elimination half-lives of about 19 and 15 hours, respectively, have been measured.

**5.3 Preclinical safety data**

Single and repeat dose toxicity studies were performed in mice, rats and dogs. In addition, reproduction toxicity in rats, carcinogenicity in mice and rats and *in vivo* and *in vitro* genotoxicity were examined.

The general toxicity profile, as seen with high doses of tamsulosin, is consistent with the known pharmacological actions of the α-adrenoceptor antagonists.

At very high dose levels the ECG was altered in dogs. This response is considered to be not clinically relevant. Tamsulosin showed no relevant genotoxic properties.

Increased incidences of proliferative changes of mammary glands of female rats and mice have been reported. These findings, which are probably mediated by hyperprolactinemia and only occurred at high dose levels, are regarded as irrelevant.

**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipient(s)**

Macrogol 7.000.000.

Macrogol 8.000.

Magnesium stearate (E470b).

Opadry yellow 03f22733
6.2 Incompatibilities
Not applicable.

6.3 Shelf life
4 years.

6.4 Special precautions for storage
Store below 30°C.

6.5 Nature and contents of container
Aluminium / aluminium foil blister packs containing 30 tablets.

6.6 Special precautions for disposal and other handling
No special requirements.

7. MARKETING AUTHORISATION HOLDER
SAJA Pharmaceuticals
Saudi Arabian Japanese pharmaceutical company limited
Jeddah – Saudi Arabia
Under license from
ASTELLAS PHARMA INC
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