SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Flomax Relief® MR

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains as active ingredient tamsulosin hydrochloride 400 microgram, equivalent to 367 microgram tamsulosin.

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Capsule modified release, hard (capsule). Orange/olive green coded with T0.4 and the company logo.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of functional symptoms of benign prostatic hyperplasia (BPH).

4.2 Posology and method of administration

Male 45 to 75 years.

One capsule daily, to be taken after the same meal each day.

The capsule should be swallowed whole and should not be crunched or chewed as this will interfere with the modified release of the active ingredient.

4.3 Contraindications

Hypersensitivity to tamsulosin hydrochloride, including drug-induced angioedema, or any other component of the product; a history of orthostatic hypotension; severe hepatic insufficiency.

4.4 Special warnings and precautions for use

As with other alpha1 blockers, a reduction in blood pressure can occur in individual cases during treatment with Flomax Relief, 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.

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 (e.g. ketoconazole) in patients with poor metaboliser CYP2D6 phenotype.

Tamsulosin hydrochloride should be used with caution in combination with strong (e.g. ketoconazole) and moderate (e.g. erythromycin) inhibitors of CYP3A4 (see section 4.5).

Additional warnings when supplied as a non-prescription medicine:

Flomax Relief should not be given to patients receiving antihypertensive medicines with significant alpha1-adrenoceptor antagonist activity (e.g. doxazosin, indoramin, prazosin, terazosin, verapamil) without first consulting a doctor.

Flomax Relief should not be given to a man who experiences postural hypotension.

Flomax Relief should not be supplied to any man with heart, renal, or liver disease, uncontrolled diabetes, urinary incontinence, or to a man who has had prostate surgery.

Flomax Relief should not be supplied to a man whose symptoms are of less than 3 months duration.

Flomax Relief should not be given to any man who reports dysuria, haematuria, or cloudy urine, in the past 3 months, or who is suffering from a fever that might be related to a urinary tract infection.

Flomax Relief should not be used in those planning to have eye surgery for cataract or glaucoma, or who have recently experienced blurred or cloudy vision that has not been examined by a GP or Optician.

If urinary symptoms have not improved within 14 days of starting treatment with Flomax Relief, or are getting worse, the patient should stop taking Flomax Relief and be referred to the doctor.

Medical review is required for the diagnosis of BPH. Patients must see their doctor within 6 weeks of starting treatment, for assessment of their symptoms and confirmation that they can continue to take Flomax Relief from their Pharmacist.

Every 12 months, patients should be advised to consult a doctor for a clinical review.

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 Flomax Relief was given concomitantly with either atenolol, enalapril, or theophylline. Concomitant cimetidine brings about a rise in plasma levels of tamsulosin, and furosemide a fall, but as levels remain within the normal range posology need not be changed.

In vitro neither diazepam nor propranolol, trichlormethiazide, chlormadinon, amitryptyline, 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.

Diclofenac and warfarin, however, may increase the elimination rate of tamsulosin.

Concomitant administration of tamsulosin hydrochloride with strong inhibitors of CYP3A4 may lead to increased exposure to tamsulosin hydrochloride. Concomitant administration with ketoconazole (a known strong CYP3A4 inhibitor) resulted in an increase in AUC and Cmax of tamsulosin hydrochloride by a factor of 2.8 and 2.2 respectively.

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.

Concomitant administration of tamsulosin hydrochloride with paroxetine, a strong inhibitor of CYP2D6, resulted in a Cmax 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.

There is a theoretical risk of enhanced hypotensive effect when given concurrently with drugs which may reduce blood pressure including anaesthetic agents, other alpha1-adrenoceptor antagonists.

4.6 Fertility, Pregnancy and lactation

Flomax Relief is not indicated for use in women.

Ejaculation disorders have been observed in short and long term clinical studies with tamsulosin. Events of ejaculation disorder, retrograde ejaculation and ejaculation failure have been reported in the post authorisation phase.

4.7 Effects on ability to drive and use machines

No data is available on whether Flomax Relief adversely affects the ability to drive or operate machines. However, in this respect patients should be aware of the fact that drowsiness, blurred vision, dizziness and syncope can occur.

4.8 Undesirable effects

System Organ Class	Common (>1/100, <1/10)	Uncommon (>1/1 000, <1/100)	Rare (>1/10 000, <1/1 000)	Very rare (<1/10 000)	Not Known (cannot be estimated from the available data)
Nervous system disorders	dizziness (1.3%)	headache	syncope		
Eye disorders					Vision blurred* Visual impairment *
Cardiac disorders		palpitations			
Vascular disorders		orthostatic hypotension			
Respiratory, thoracic and mediastinal disorders		rhinitis			Epistaxis*
Gastro-intestinal disorders		constipation, diarrhoea, nausea, vomiting			Dry Mouth*
Skin and subcutaneous tissue disorders		rash, pruritus, urticaria	angioedema	Stevens-Johnson syndrome	Erythema multiforme * Dermatitis exfoliative*
Reproductive systems and breast disorders	ejaculation disorders, including retrograde ejaculation and ejaculation failure			priapism	
General disorders and administration site disorders		asthenia			

*observed post-marketing.

As with other alpha-blockers, drowsiness or oedema can occur.

During cataract and glaucoma 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 estimated from the available data.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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.

Treatment:

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 sulfate, can be administered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Alpha1-adrenoceptor antagonist.

Preparations for the exclusive treatment of prostatic disease.

Mechanism of action:

Tamsulosin binds selectively and competitively to postsynaptic alpha1-receptors, in particular to the subtype alpha1A, which bring about relaxation of the smooth muscle of the prostate, whereby tension is reduced.

Pharmacodynamic effects:

Flomax Relief increases maximum urinary flow rate by reducing smooth muscle tension in prostate and urethra and thereby relieving obstruction.

It also improves the complex of irritative and obstructive symptoms in which bladder instability and tension of the smooth muscles of the lower urinary tract play an important role. Alpha1-blockers can reduce blood pressure by lowering peripheral resistance. No reduction in blood pressure of any clinical significance was observed during studies with Flomax Relief.

5.2 Pharmacokinetic properties

Absorption:

Tamsulosin hydrochloride is absorbed from the intestine and is almost completely bioavailable.

Absorption of tamsulosin hydrochloride is reduced by a recent meal.

Uniformity of absorption can be promoted by the patient always taking Flomax Relief after the same meal each day.

Tamsulosin shows linear kinetics.

After a single dose of Flomax Relief in the fed state, plasma levels of tamsulosin peak at around 6 hours and, in the steady state, which is reached by day 5 of multiple dosing, Cmax in patients is about two thirds higher than that reached after a single dose. Although this was seen in elderly patients, the same finding would also be expected in young ones.

There is a considerable inter-patient variation in plasma levels both after single and multiple dosing.

Distribution:

In man, tamsulosin is about 99% bound to plasma proteins and volume of distribution is small (about 0.2 l/kg).

Biotransformation:

Tamsulosin has a low first pass effect, being metabolised slowly. Most tamsulosin is present in plasma in the form of unchanged drug. It is metabolised in the liver.

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 metabolising enzymes may lead to increased exposure to tamsulosin hydrochloride (see sections 4.4 and 4.5).

No dose adjustment is warranted in hepatic insufficiency.

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

Elimination:

Tamsulosin and its metabolites are mainly excreted in the urine with about 9% of a dose being present in the form of unchanged drug.

After a single dose of Flomax Relief in the fed state, and in the steady state in patients, elimination half-lives of about 10 and 13 hours respectively have been measured.

The presence of renal impairment does not warrant lowering the dose.

5.3 Preclinical safety data

Single and repeat dose toxicity studies were performed in mice, rats and dogs. In addition reproduction toxicity studies were performed 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 alpha-adrenergic blocking agents. 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 hyperprolactinaemia and only occurred at high dose levels are regarded as irrelevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Flomax Relief modified release capsules contain the following excipients:

Content of capsule:

- microcrystalline cellulose
- methacrylic acid-ethyl acrylate copolymer
- polysorbate 80
- sodium laurilsulfate
- triacetin
- calcium stearate
- talc

Capsule shell:

- hard gelatin
- indigotine E132
- titanium dioxide E171
- yellow iron oxide E172
- red iron oxide E172

Printing ink:

- shellac
- propylene glycol
- black iron oxide E172

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life as packaged for sale:

Flomax Relief modified release capsules can be used up to four years after manufacture. The expiry date is printed on the package.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

Polypropylene-aluminium blister packs containing 7 capsules per strip; cardboard boxes containing 14 and 28 capsules.

6.6 Special precautions for disposal

No special instructions.

7 MARKETING AUTHORISATION HOLDER

Opella Healthcare UK Limited, trading as Sanofi,
410 Thames Valley Park Drive,
Reading,
Berkshire,
RG6 1PT,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 53886/0033

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