Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Prostaflo® -F

Tamsulosin Hydrochloride (Sustained release) & Finasteride Capsules

2. Qualitative and quantitative composition

Each hard gelatin capsule contains:

Tamsulosin Hydrochloride USP (as sustained release pellets)	0.4mg
Finasteride USP (as film coated tablet)	5mg
Excipients	q.s.

Colour: Lake of Indigo Carmine and Titanium Dioxide USP

(for the full list of excipients, see section 6.1)

3. Pharmaceutical form:

Hard Gelatin Capsule

A pink/CT Hard gelatin capsule of size "1" containing off-white to white coloured pellets and a blue coloured round shaped, biconvex film coated tablet.

4. Clinical particulars

4.1 Therapeutic indications

Treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH).

Reduction in the risk of acute urinary retention (AUR) and surgery in patients with moderate to severe symptoms of Benign Prostatic Hyperplasia (BPH).

4.2 Posology and method of administration

Posology

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

Method of administration

For oral use only

4.3 Contraindications

Hypersensitivity to finasteride or to any of the excipients.

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

Women, children and adolescents.

4.4 Special warnings and precautions for use

It 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.

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

Inhibitors of CYP3A4 and CYP2D6
Concomitant administration of tamsulosin hydrochloride with strong inhibitors of CYP3A4 (e.g. ketoconazole), or to a lesser extent, with strong inhibitors of CYP2D6 (e.g. paroxetine) can increase tamsulosin exposure. Tamsulosin hydrochloride is therefore not recommended in patients taking a strong CYP3A4 inhibitor and should be used with caution in patients taking a moderate CYP3A4 inhibitor, a strong or moderate CYP2D6 inhibitor, a combination of both CYP3A4 and CYP2D6 inhibitors, or in patients known to be poor metabolisers of CYP2D6.

Mood alterations and depression
Mood alterations including depressed mood, depression and less frequently, suicidal ideation have been reported in patients treated with finasteride 1 mg. patient should be monitored for psychiatric symptoms and if these occur, treatment with finasteride should be discontinued and the patient advised to seek medical advice.

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

4.5 Interaction with other medicinal products and other forms of interaction.

No drug interactions of clinical importance have been identified. Finasteride is metabolized primarily via, but does not affect the cytochrome P450-linked drug metabolizing enzyme system. Although the risk for finasteride to affect the pharmacokinetics of other drugs is estimated to be small, it is probable that inhibitors and inducers of cytochrome P450 3A4 will affect the plasma concentration of finasteride. However, based on established safety margins, any increase due to concomitant use of such inhibitors is unlikely to be of clinical significance. Compounds which have been tested in man have included antipyrine, digoxin, glibenclamide, propranolol, theophylline and warfarin and no interactions were found.

Concomitant administration of tamsulosin hydrochloride with drugs which can reduce blood pressure, including anaesthetic agents, PDE5 inhibitors and other alpha1-adrenoceptor antagonists could lead to enhanced hypotensive effects. Dutasteride/tamsulosin should not be used in combination with other alpha-adrenoceptor antagonists.
Concomitant administration of tamsulosin hydrochloride and ketoconazole (a strong CYP3A4 inhibitor) resulted in an increase of the Cmax and AUC of tamsulosin hydrochloride by a factor of 2.2 and 2.8 respectively. Concomitant

administration of tamsulosin hydrochloride and paroxetine (a strong CYP2D6 inhibitor) resulted in an increase of the Cmax and AUC of tamsulosin hydrochloride by a factor of 1.3 and 1.6 respectively. A similar increase in exposure is expected in CYP2D6 poor metabolizers compared to extensive metabolizers when co-administered with a strong CYP3A4 inhibitor. The effects of co-administration of both CYP3A4 and CYP2D6 inhibitors with tamsulosin hydrochloride have not been evaluated clinically, however there is a potential for significant increase in exposure to tamsulosin exposure.

Concomitant administration of tamsulosin hydrochloride (0.4 mg) and cimetidine (400 mg every six hours for six days) resulted in a decrease in the clearance (26%) and an increase in the AUC (44%) of tamsulosin hydrochloride. Caution should be used when tamsulosin hydrochloride is used in combination with cimetidine.
A definitive drug–drug interaction study between tamsulosin hydrochloride and warfarin has not been conducted. Results from limited in vitro and in vivo studies are inconclusive. Diclofenac and warfarin, however, may increase the elimination rate of tamsulosin. Caution should be exercised with concomitant administration of warfarin and tamsulosin hydrochloride.

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

4.6 Fertility, pregnancy and lactation

It is contraindicated for use by women. There have been no studies to investigate the effect on pregnancy, lactation and fertility.

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 informed about the possible occurrence of symptoms related to orthostatic hypotension such as dizziness when taking it.

4.8 Undesirable effects

Erectile dysfunction, ejaculation disorder (including decreased volume of ejaculate), Hypersensitivity reactions, including rash, pruritus, urticaria and angioedema (swelling of the lips, tongue, throat, and face).
Gynaecomastia, decreased libido, impotence, reduction in the vol of ejaculate, genital abnormalities in the male foetus of pregnant women exposed to finasteride. Hypersensitivity reactions such as swelling of lips and rashes, postural hypotension, dizziness and vertigo; headache, infection, asthenia, back pain, chest pain, dizziness, somnolence, insomnia, decreased libido, rhinitis, pharyngitis, cough, sinusitis, diarrhoea, nausea, tooth disorder, amblyopia.

Intraoperative Floppy Iris Syndrome (IFIS), a variant of small pupil syndrome, during cataract surgery have been associated with alpha1- adrenoceptor antagonists, including tamsulosin.
In addition atrial fibrillation, arrhythmia, tachycardia, dyspnoea, epistaxis, vision blurred, visual impairment, erythema multiforme, dermatitis exfoliative, ejaculation disorder, retrograde ejaculation, ejaculation failure and dry mouth have been reported in association with tamsulosin use. The frequency of events and the role of tamsulosin in their causation cannot be reliably determined.

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 pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 Overdose
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.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Finasteride is a 4-azasteroid, which inhibits human Type 2 5α-reductase (present within the hair follicles) with greater than 100-fold selectivity over human Type 1 5α-reductase, and blocks the peripheral conversion of testosterone to the androgen dihydrotestosterone (DHT).
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.

5.2 Pharmacokinetic properties
The oral bioavailability of finasteride is approximately 80%. The bioavailability is not affected by food. Maximum finasteride plasma concentrations are reached approximately two hours after dosing and the absorption is complete after six to eight hours. Protein binding is approximately 93%. Finasteride is metabolized primarily via but does not affect the cytochrome P450 3A4 system. it was excreted in the urine in the form of metabolites (virtually no

unchanged drug was excreted in the urine) and 57% of total dose was excreted in the faeces. Tamsulosin hydrochloride is absorbed from the intestine and is almost completely bioavailable. Absorption of tamsulosin hydrochloride is reduced by a recent meal. In man, tamsulosin is about 99% bound to plasma proteins and volume of distribution is small (about 0.2 l/kg). Tamsulosin and its metabolites are mainly excreted in the urine with about 9% of a dose being present in the form of unchanged drug.

5.3 Preclinical safety data
Non-clinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity, genotoxicity, and carcinogenic potential.

6. Pharmaceutical particulars
6.1 List of Excipients:
Sodium starch glycolate
Lactose
Pregelatinized starch
Maize starch
Sodium lauryl sulphate
Povidone K-30
Microcrystalline cellulose 112
Magnesium stearate
Ready mix of white (film coating)
Indigo carmine Lake
Empty hard gelatin capsule size "1" Pink/CT

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store below 30° C. Protect from direct sunlight, heat & moisture.

6.5 Nature and contents of container
Prostaflo®-F is available as 3 x 10 tablets in Alu-Alu blister pack.

6.6 Special precautions for disposal and other handling
Any unused medicine product or waste material should be disposed of in accordance with the local requirements.

7. Marketing authorization holder and manufacturing site addresses
Manufactured in India by:
RELAX BIOTECH PVT. LIMITED.
862/1, G.I.D.C, Makarpura,
Vadodara – 390 010, Gujarat, India.

Manufactured for & Marketed by:
KRISHNA CHEMISTS LTD.
P.O. BOX 3328-00506
NAIROBI, KENYA.

8. Marketing Authorization Number
H2017/CTD4118/148

9. Date of first authorization/renewal of the authorization
Date of first authorization: 05/05/2017

10. Date of revision of the text
11/11/2025