

SUMMARY OF THE PRODUCT CHARACTERISTICS

1. Name of Medicinal Product

Tamcontin 0.4

(Controlled Release Tablets of Tamsulosin Hydrochloride)

2. Qualitative and Quantitative Composition

Core

Name of ingredients	Unit formula (mg/tablet)	Active/ Non-active	Reference to standard	Reason for inclusion
Tamsulosin Hydrochloride	0.412*	Active	In-house	Alpha-adrenoreceptor antagonists
Kolliwax CSA 50 (Cetostearyl Alcohol)	10.00	Non-Active	BP	Release Retardant
Lactose	60.00	Non-Active	BP	Diluent
Povidone K-30	4.00	Non-Active	USP	Binder
Magnesium Stearate	1.00	Non-Active	BP	Lubricant
Microcrystalline Cellulose	31.588	Non-Active	BP	Diluent
Hydroxyethylcellulose (Natrosol 250 HX)	10.00	Non-Active	BP	Release Retardant
Purified Talc	1.00	Non-Active	BP	Glident
Purified Water	64.0**	Non-Active	BP	Solvent

* Contain 3% Overage

** Not present in final weight

Coating

Name of ingredients	Unit formula (mg / tablet)	Active / Non-active	Reference to standard	Reason for inclusion
Acryl-Eze 93 O 18359 White	10.00	Non-Active	In-house	Acid protective coating material
Purified Water	56.7***	Non-Active	BP	Solvent

***Not present in final weight

3. Pharmaceutical Form

Controlled Release Tablets (Oral)

Description: White to off-white, round, biconvex, enteric-coated tablets with ‘.4’ engraved on one of the facets.

4. Clinical Particulars

4.1 Therapeutic Indications

For the treatment of symptoms of benign prostatic hyperplasia (BPH). Not indicated for the treatment of hypertension.

4.2 Posology and Method of Administration

Dosage of 0.4 mg once daily is recommended for the treatment of signs and symptoms of benign prostatic hyperplasia (BPH). The tablet is to be swallowed whole and not crushed or chewed. It should be administered approximately at half an hour following the same meal each day.

For those patients who fail to respond to the 0.4 mg dose after two to four weeks of dosing, the dose of tamsulosin tablets can be increased to 0.8 mg once daily. If therapy is discontinued or interrupted for several days at either the 0.4 mg or 0.8 mg dose, therapy should be started again with the 0.4 mg once daily dose.

4.3 Contraindications

Hypersensitivity to tamsulosin hydrochloride or any other component of the formulation. History of orthostatic hypotension and severe hepatic insufficiency.

4.4 Special warnings and special precautions for use

As with other alpha-1 blockers, a reduction in blood pressure can occur during treatment as a result of which, rarely, syncope may occur. At the first signs of orthostatic hypotension such as dizziness or weakness, the patient should sit or lie down until the symptoms have disappeared.

Patients should be evaluated prior to the start of the therapy to rule out the presence of carcinoma of the prostate. Digital rectal examination and when necessary, determination of prostate specific antigen (PSA) should be performed before treatment and at regular intervals afterwards.

Very rarely, like with other alpha adrenoreceptor antagonists, priapism can occur. Because this condition can lead to permanent impotence if not properly treated, patients must be advised about the seriousness of the condition.

The treatment of patients with severe renal impairment (creatinine clearance of less than 10ml/min) should be done with caution as studies with such patients have not been done.

Intraoperative Floppy Iris Syndrome (IFIS): IFIS, a variant of small pupil syndrome, has been observed during cataract surgery in some patient treated with alpha-1 blocker. Most reports were in patients taking the alpha-1 blocker when IFIS occurred, but in some cases, the alpha-1-blocker had been stopped prior to surgery (2 to 14 days). In a few cases, IFIS was reported after the patient had been off the alpha-1 blocker for a longer period (5 weeks to 9 months).

The patient's ophthalmologist should be prepared for possible modification to their surgical technique such as the utilization of iris hooks, iris dilator rings or viscoelastic substances. The benefit of stopping alpha -1 blocker therapy prior to cataract surgery has not been established.

Sulfa allergy: In patients with sulfa allergy, allergic reaction to tamsulosin hydrochloride has been rarely reported. If a patient reports a serious or life-threatening sulfa allergy, caution is warranted when administering tamsulosin hydrochloride.

Children:

Not indicated for use in paediatric population.

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

Though there are no studies on the pharmacokinetic or the pharmacodynamic interactions between tamsulosin and other adrenergic blocking agents, there is a theoretical risk of enhanced hypotensive effect when given concurrently with drugs which may reduce blood pressure, including anaesthetic agents and other alpha-1 adrenoreceptor antagonists.

Concurrent administration with sildenafil, tadalafil and vardenafil may also increase the risk of a drop in blood pressure. Doses of sildenafil greater than 25 mg should be taken at least four hours apart from taking tamsulosin.

Concomitant cimetidine causes a rise in the plasma levels and a decrease in the clearance of tamsulosin, therefore caution is advised, particularly at doses higher than 0.4mg. Frusemide leads to a fall in the plasma levels of tamsulosin.

No interactions were observed when tamsulosin was given concomitantly with atenolol, enalapril, nifedipine, digoxin or theophylline.

In vitro studies show that diazepam, propranolol, trichlormethiazide, chlormadinon, amitriptyline, diclofenac, glibenclamide, warfarin and simvastatin do not change the free fraction of tamsulosin in the human plasma and vice versa. No interactions at the level of hepatic metabolism have been seen during in vitro studies with liver microsomal fractions involving salbutamol, glibenclamide, amitriptyline and finasteride. Diclofenac and warfarin may however increase the elimination rate of tamsulosin.

4.6 Pregnancy and Lactation

Not applicable as tamsulosin is intended for male patients only.

4.7 Effects on ability to drive and use machines.

No data is available on whether Tamcontin 0.4 tablets adversely affect 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

The following adverse reactions have been reported during the use of tamsulosin: dizziness, abnormal ejaculation and, less frequently (1-2%) headache, asthenia, postural hypotension, palpitations and rhinitis.

Gastrointestinal reactions such as nausea, vomiting, diarrhea, and constipation occasionally occur. Hypersensitivity reactions such as rash, pruritus, and urticaria can occur occasionally. As with other alpha-blockers, drowsiness, blurred vision, dry mouth or oedema can occur. Syncope has been reported rarely, and there have been very rare reports of angioedema and priapism.

4.9 Overdose

No cases of acute overdosage have been reported. However, acute hypotension could theoretically occur after overdosage in which case cardiovascular support should be given. Blood pressure should 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, vasopressor should be employed. Renal functions 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 undertaken 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

Tamsulosin hydrochloride is an Alpha-1 adrenoreceptor antagonist. It binds selectively and competitively to postsynaptic alpha-1 receptors, in particular to the subtype alpha_{1A} receptors, which bring about relaxation of the smooth muscle of the prostate and urethra, whereby tension is reduced.

Tamsulosin increases maximum urinary flow rate by reducing smooth muscle tension in prostate and urethra and thereby relieving obstruction. It also improves the irritative and obstructive symptoms in which bladder instability and tension of the smooth muscles of the lower urinary tract play an important role. Alpha-1 blockers can reduce blood pressure by lowering peripheral resistance. The reduction in blood pressure is not clinically significant as observed during studies with tamsulosin.

5.2 Pharmacokinetic Properties

The pharmacokinetics of tamsulosin hydrochloride have been evaluated in adult healthy volunteers and patients with BPH after single and/or multiple administration with doses ranging from 0.1 mg to 1 mg. Absorption of tamsulosin is essentially complete following oral administration under fasting conditions (>90%). It exhibits linear kinetics following single or multiple dosing, with achievement of steady state concentrations on the fifth day of once-a-day dosing.

Tamsulosin is 99% bound to plasma proteins. The time to reach maximum concentration is four to five hours under fasting conditions and six to seven hours when it is administered with food. Absorption is reduced by a recent meal before the dose, but the uniformity of absorption can be promoted by taking the drug after the same meal everyday. Tamsulosin is extensively metabolized by the cytochrome P450 enzymes in the liver and less than 10% of the dose is excreted in the urine unchanged. On administration of the radiolabelled dose of tamsulosin to four healthy volunteers, 97% of the administered radioactive substance was recovered, with urine (76%) representing the primary route of excretion compared to faeces (21%) over 168 hours. Following intravenous or oral administration of an immediate release formulation, the elimination half life of tamsulosin in plasma ranges from 5 to 7 hours. Because of the absorption rate-controlled pharmacokinetics with controlled release tamsulosin tablets, the apparent half life of tamsulosin is approximately 9 to 13 hours in healthy volunteers and 14 to 15 hours in the target population.

Pharmacokinetic studies indicate that disposition of tamsulosin may be slightly prolonged in geriatric males as compared to young healthy male volunteers. Therefore, greater sensitivity of some older individuals cannot be ruled out. Patients with mild to moderate renal and hepatic impairment do not require any dosage adjustment but those with end stage renal disease have not been studied.

5.3 Preclinical safety data

Not Applicable

6. Pharmaceutical Particulars

6.1 List of Excipients

Excipients
Kolliwax CSA 50 (Cetostearyl Alcohol)
Lactose
Povidone K-30
Magnesium Stearate
Microcrystalline Cellulose
Hydroxyethylcellulose (Natrosol 250 HX)
Purified Talc
Purified Water
Acryl-Eze 93 O 18359 White

6.2 Incompatibilities

None of the incompatibilities has been reported.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 30° C, in a dry place, protected from light.
Keep out of reach of children.

6.5 Nature and content of container

Tamcontin 0.4 are packed in an aluminium strip made up of printed aluminium foil (width 131 mm × thickness 0.04 mm) and plain aluminium foil (width 131 mm × thickness 0.04 mm).

Box of 100 Tablets (10x10's strips)

6.6 Instructions for use/handling

Keep out of reach of children,

The tablets should be swallowed whole and not chewed.

7.0 Name and address of marketing authorization holder

Manufactured by:

Modi-Mundipharma Pvt. Ltd.

Modipuram – 250 110,

U.P., India

Phone: +91-121-2576214-17

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Registered by:

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1400, Modi Tower,

98, Nehru Place,

New Delhi – 110019, India.

Phone: +91-11-42504555

Fax: +91-11-26451659

E-mail: mithu.sen@winmedicare

8.0 Marketing authorization number

Rwanda FDA-HMP-MA-0640

9.0 Date of first authorization/renewal of the authorization

02/12/2023

10.0 Date of (partial) revision of the text

December 2023