To be sold by retail on the prescription of a Registered Medical Practitioner Only.

Dr.Reddy's

Alfuzosin Hydrochloride Extended Release & Tadalafil Tablets

ALFOO®-T

APPROVED

1. GENERIC NAME
Alfuzosin Hydrochloride Extended Release & Tadalafil Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each Film Coated Bilayered Tablet Contains:
Alfuzosin Hydrochloride IP.....**10.0mg**
(As Extended Release Form)
Tadalafil IP.....**5mg**
Colour: Sunset Yellow FCF Lake

3. DOSAGE FORM AND STRENGTH
Bilayer tablet, 10.0 mg + 5 mg

4. CLINICAL PARTICULARS
4.1 THERAPEUTIC INDICATION
For the treatment of patients with Lower urinary Tract Symptoms (LUTS) associated with benign Prostatic Hyperplasia (BPH)

4.2 Posology and method of administration
Posology
The recommended dose is 1 tablet once daily or as directed by the Physician.

Method of administration: For oral use.

4.3 CONTRAINDICATIONS
Alfuzosin
Hypersensitivity to the active substance, other quinazolines (e.g. terazosin, doxazosin) or to any of the excipients
- Conditions with orthostatic hypotension.
- Liver insufficiency.
- Combination with other alpha1-receptor blockers.

Tadalafil
Hypersensitivity to the active substance or to any of the excipients..
In clinical studies, tadalafil was shown to augment the hypotensive effects of nitrates. This is thought to result from the combined effects of nitrates and tadalafil on the nitric oxide/cGMP pathway. Therefore, administration of Tadalafil to patients who are using any form of organic nitrate is contraindicated. Tadalafil must not be used in men with cardiac disease for whom sexual activity is inadvisable. Physicians should consider the potential cardiac risk of sexual activity in patients with pre-existing cardiovascular disease.
The following groups of patients with cardiovascular disease were not included in clinical trials and the use of tadalafil is therefore contraindicated:
- patients with myocardial infarction within the last 90 days,
- patients with unstable angina or angina occurring during sexual intercourse,
- patients with New York Heart Association Class 2 or greater heart failure in the last 6 months,
- patients with uncontrolled arrhythmias, hypotension (< 90/50 mm Hg), or uncontrolled hypertension,
- patients with a stroke within the last 6 months.
Tadalafil is contraindicated in patients who have loss of vision in one eye because of non-arteritic anterior ischaemic optic neuropathy (NAION), regardless of whether this episode was in connection or not with previous PDE5 inhibitor exposure. The co-administration of PDE5 inhibitors, including tadalafil, with guanylate cyclase stimulators, such as riociguat, is contraindicated as it may potentially lead to symptomatic hypotension

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Alfuzosin
Patients with severe renal impairment
Alfuzosin should not be given to patients with severe renal impairment (creatinine clearance < 30ml/min) in view of the lack of clinical safety data in this group of patients.
Risk of hypotension
Xatger should be given with caution to patients who are on antihypertensive medication or nitrates. Blood pressure should be monitored regularly, especially at the beginning of treatment.
In some subjects postural hypotension may develop, with or without symptoms (dizziness, fatigue, asthenia, sweating) within a few hours following administration. In such cases, the patient should lie down until the symptoms have totally disappeared. These effects are usually transient, occur in the beginning of treatment and do not usually prevent the continuation of treatment. Pronounced drop in blood pressure has been reported in post-marketing surveillance in patients with pre-existing risk factors (such as underlying cardiac diseases and/or concomitant treatment with anti-hypertensive medication). The risk of developing hypotension and related adverse reactions may be greater in older people. Patients should be warned about the possibility of these effects. Care should be taken when alfuzosin is administered to patients who have had a pronounced hypotensive response to another alpha1-receptor blocker. In coronary patients, the specific treatment for coronary insufficiency should be continued. If angina pectoris reappears or worsens, alfuzosin should be discontinued. Concomitant administration of specific treatment for coronary insufficiency such as nitrates and alfuzosin may increase the risk of occurrence of hypotension.
Cardiac failure
As with all alpha1-receptor blockers, alfuzosin should be used with caution in patients with acute cardiac failure.
QTc prolongation Patients with congenital QTc prolongation, with a known history of acquired QTc prolongation or who are taking drugs known to increase the QTc interval should be evaluated before and during the administration of alfuzosin.

Tadalafil
Before treatment with Tadalafil
A medical history and physical examination should be undertaken to diagnose erectile dysfunction or benign prostatic hyperplasia and determine potential underlying causes, before pharmacological treatment is considered. Prior to initiating any treatment for erectile dysfunction, physicians should consider the cardiovascular status of their patients, since there is a degree of cardiac risk associated with sexual activity. Tadalafil has vasodilator properties, resulting in mild and transient decreases in blood pressure (see sect and as such potentiates the hypotensive effect of nitrates. The evaluation of erectile dysfunction should include a determination of potential underlying causes and the identification of appropriate treatment following an appropriate medical assessment. It is not known if Tadalafil is effective in patients who have undergone pelvic surgery or radical non-nerve-sparing prostatectomy Tadalafil 5 mg - Prior to initiating treatment with tadalafil for benign prostatic hyperplasia patients should be examined to rule out the presence of carcinoma of the prostate and carefully assessed for cardiovascular conditions
Cardiovascular
Serious cardiovascular events, including myocardial infarction, sudden cardiac death, unstable angina pectoris, ventricular arrhythmia, stroke, transient ischaemic attacks, chest pain, palpitations and tachycardia, have been reported either post marketing and/or in clinical trials. Most of the patients in whom these events have been reported had pre-existing cardiovascular risk factors. However, it is not possible to definitively determine whether these events are related directly to these risk factors, to Tadalafil, to sexual activity, or to a combination of these or other factors. Tadalafil 2.5 mg and 5 mg - In patients receiving concomitant antihypertensive medicinal products, tadalafil may induce a blood pressure decrease. When initiating daily treatment with tadalafil, appropriate clinical considerations should be given to a possible dose adjustment of the antihypertensive therapy. In patients who are taking alpha1 blockers, concomitant administration of Tadalafil may lead to symptomatic hypotension in some patients. The combination of tadalafil and doxazosin is not recommended
Vision
Visual defects, including Central Serous Chorioretinopathy (CSCR), and cases of NAION have been reported in connection with the intake of Tadalafil and other PDE5 inhibitors. Most cases of CSCR resolved spontaneously after stopping tadalafil. Regarding NAION, analyses of observational data suggest an increased risk of acute NAION in men with erectile dysfunction following exposure to tadalafil or other PDE5 inhibitors. As this may be relevant for all patients exposed to tadalafil, the patient should be advised that in case of sudden visual defect, visual acuity impairment and/or visual distortion, he should stop taking Tadalafil and consult a physician immediately.

4 .5 DRUG INTERACTION
Alfuzosin
Administration of general anaesthetics to a patient treated with alfuzosin may lead to blood pressure instability. It is recommended that the tablets be withdrawn 24 hours before surgery. No pharmacodynamic or pharmacokinetic interactions have been observed in studies with healthy volunteers between alfuzosin and the following active substances: warfarin, digoxin, hydrochlorothiazide and atenolol.
Combinations contra-indicated:
- Alpha1-receptor blockers

Concomitant use not recommended:
- Potent CYP3A4 inhibitors such as itraconazole, ketoconazole, protease inhibitors, clarithromycin, telithromycin and nefazodone since alfuzosin blood levels are increased.

Ketoconazole
Repeated 200 mg daily dosing of ketoconazole, for seven days resulted in a 2.1-fold increase in Cmax and a 2.5-fold increase in exposure of alfuzosin 10 mg prolonged-release tablets when administered under fed conditions. Other parameters such as tmax and t1/2 were not modified. The increase in alfuzosin Cmax and AUC(last) following repeated 400 mg daily administration of ketoconazole was 2.3-fold and 3.2-fold respectively.
Combinations to be taken into account:
- Antihypertensive drugs
- Nitrates
- Patients being treated with alfuzosin must be haemodynamically stable before treatment with a phosphodiesterase-5 inhibitor (sildenafil, tadalafil, vardenafil) is initiated.

Tadalafil
Interaction studies were conducted with 10 mg and/or 20 mg tadalafil, as indicated below. With regard to those interaction studies where only the 10 mg tadalafil dose was used, clinically relevant interactions at higher doses cannot be completely ruled out.
Effects of Other Substances on Tadalafil
Cytochrome P450 inhibitors
Tadalafil is principally metabolised by CYP3A4. A selective inhibitor of CYP3A4, ketoconazole (200 mg daily), increased tadalafil (10 mg) exposure (AUC) 2-fold and Cmax by 15 %, relative to the AUC and Cmax values for tadalafil alone. Ketoconazole (400 mg daily) increased tadalafil (20 mg) exposure (AUC) 4-fold and Cmax by 22 %. Ritonavir, a protease inhibitor (200 mg twice daily), which is an inhibitor of CYP3A4, CYP2C9, CYP2C19, and CYP2D6, increased tadalafil (20 mg) exposure (AUC) 2-fold with no change in Cmax. Although specific interactions have not been studied, other protease inhibitors, such as saquinavir, and other CYP3A4 inhibitors, such as erythromycin, clarithromycin, itraconazole and grapefruit juice, should be co-administered with caution, as they would be expected to increase plasma concentrations of tadalafil.
Transporters
The role of transporters (for example, p-glycoprotein) in the disposition of tadalafil is not known. Therefore, there is the potential of drug interactions mediated by inhibition of transporters.
Cytochrome P450 inducers
A CYP3A4 inducer, rifampicin, reduced tadalafil AUC by 88 %, relative to the AUC values for tadalafil alone (10 mg). This reduced exposure can be anticipated to decrease the efficacy of tadalafil; the magnitude of decreased efficacy is unknown. Other inducers of CYP3A4, such as phenobarbital, phenytoin and carbamazepine, may also decrease plasma concentrations of tadalafil.

4.6 USE IN SPECIAL POPULATION (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)
Not relevant
Tadalafil is not indicated for use by women.
Pregnancy
There are limited data from the use of tadalafil in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. As a precautionary measure, it is preferable to avoid the use of Tadalafil during pregnancy.
Breastfeeding
Available pharmacodynamic/toxicological data in animals have shown excretion of tadalafil in milk. A risk to the suckling child cannot be excluded. Tadalafil should not be used during breast feeding.
Fertility
Effects were seen in dogs that might indicate impairment of fertility. Two subsequent clinical studies suggest that this effect is unlikely in humans, although a decrease in sperm concentration was seen in some men.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
There are no data available on reduced reaction ability. Adverse reactions such as vertigo, dizziness and asthenia may occur, essentially at the beginning of treatment. This has to be taken into consideration when driving vehicles and operating machines.
Tadalafil has negligible influence on the ability to drive or use machines. Although the frequency of reports of dizziness in placebo and tadalafil arms in clinical trials was similar, patients should be aware of how they react to Tadalafil before driving or using machines.

4.8 UNDESIRABLE EFFECTS
Alfuzosin
Classification of expected frequencies: Very common (≥1/10), common (≥1/100 to< 1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to< 1/1,000), very rare (<1/10,000), not known (cannot be estimated from the available data) The most commonly reported event is dizziness, which occurs in approximately 5% of treated patients.

MedDRA system organ class	Common	Uncommon	Rare	Very rare	Not known:
Blood and lymphatic system Disorders					Neutropenia, thrombocytopenia
Nervous system disorders	Faintness /dizziness, headache, tiredness	Vertigo, drowsiness, syncope*			Cerebral ischaemic disorders in patients with underlying cerebrovasculardisturbances (see section 4.4)
Eye disorders		Visual disturbances			Intraoperative floppy iris syndrome (see section 4.4)
Cardiac disorders		tachycardia, palpitations		Angina pectoris predominantly in patients with pre- existing coronary artery disease; aggravation or recurrence of angina pectoris (see section 4.4)	Atrial fibrillation
Vascular disorders		Flushing, postural hypotension*			
Respiratory, thoracic and mediastinal Disorders		Rhinitis			
Gastrointestinal disorders	Abdominal pain, nausea, dyspepsia,	Vomiting diarrhoea, dry mouth			
Hepatobiliary disorders					Hepatocellular injury, cholestatic liver disease
Skin and subcutaneoustissue disorders		Rash (urticaria, exanthema), pruritus		Angioedema,	
Renal and urinary disorders		Urinary incontinence			

*at start of treatment, with too high a dose or after short interruption of treatment

Tadalafil
Summary of the safety profile
The most commonly reported adverse reactions in patients taking Tadalafil for the treatment of erectile dysfunction or benign prostatic hyperplasia were headache, dyspepsia, back pain and myalgia, in which the incidences increase with increasing dose of Tadalafil. The adverse reactions reported were transient, and generally mild or moderate. The majority of headaches reported with Tadalafil once-a-day dosing are experienced within the first 10 to 30 days of starting treatment.
Tabulated summary of adverse reactions
The table below lists the adverse reactions observed from spontaneous reporting and in placebo-controlled clinical trials (comprising a total of 8022 patients on Tadalafil and 4422 patients on placebo) for on-demand and once-a-day treatment of erectile dysfunction and the once-a-day treatment of benign prostatic hyperplasia.
Frequency convention: Very common (≥1/10), Common (≥1/100 to < 1/10), Uncommon (≥1/1,000 to< 1/100), Rare (≥1/10,000 to< 1/1,000), Very Rare (<1/10,000) and Not known (cannot be estimated from the available

Very common	**Common**	**Uncommon**	**Rare**
Immune system disorders			
		Hypersensitivity reactions	Angioedema[2]
Nervous system disorders			
	Headache	Dizziness	Stroke[1] (including haemorrhagic events), Syncope, Transient ischaemic attacks[1], Migraine[2], Seizures, Transient amnesia
Eye disorders			
		Blurred vision, Sensations described as eye pain	Visual field defect, Swelling of eyelids, Conjunctival hyperaemia, Non-arteritic anterior ischaemic optic neuropathy (NAION)[2], Retinal vascular occlusion[2]
Ear and labyrinth disorders			
		Tinnitus	Sudden hearing loss
Cardiac disorders[1]			
		Tachycardia, Palpitations	Myocardial infarction, Unstable angina pectoris[2], Ventricular arrhythmia[2]
Vascular disorders			
	Flushing	Hypotension[3], Hypertension	
Respiratory, thoracic and mediastinal disorders			
	Nasal congestion	Dyspnoea, Epistaxis	
Gastrointestinal disorders			
	Dyspepsia	Abdominal pain, Vomiting, Nausea, Gastro-oesophageal reflux	
Skin and subcutaneous tissue disorders			
		Rash	Urticaria, Stevens-Johnson syndrome[2], Exfoliative dermatitis[2], Hyperhydrosis (sweating)
Renal and urinary disorders			
		Haematuria	
Musculoskeletal, connective tissue and bone disorders			
	Back pain, Myalgia, Pain in extremity		
Reproductive system and breast disorders			
		Prolonged erections	Priapism, Penile haemorrhage, Haematospermia
General disorders and administration site conditions			
		Chest pain[1], Peripheral oedema, Fatigue	Facial oedema[2], Sudden cardiac death[1,2]

[1] Most of the patients had pre-existing cardiovascular risk factors (see section 4.4).
[2] Postmarketing surveillance reported adverse reactions not observed in placebo-controlled clinical trials.
[3] More commonly reported when tadalafil is given to patients who are already taking antihypertensive medicinal products.

4.9 Overdose
Alfuzosin
Symptoms Hypotension, reflex tachycardia. Management In case of overdose, the patient should be hospitalised, kept in the supine position, and conventional treatment of hypotension such as addition of fluids and vasopressor drugs should take place. In case of significant hypotension, the appropriate corrective treatment may be a vasoconstrictor that acts directly on vascular muscle fibres. Administration of medicinal charcoal should be considered. Alfuzosin is highly proteinbound, therefore, dialysis may not be of benefit
Tadalafil
Single doses of up to 500 mg have been given to healthy subjects, and multiple daily doses up to 100 mg have been given to patients. Adverse events were similar to those seen at lower doses. In cases of overdose, standard supportive measures should be adopted as required. Haemodialysis contributes negligibly to tadalafil elimination.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Drugs used in benign prostatic hypertrophy, alphaadrenoreceptor antagonists, ATC code: G04CA01

Mechanism of action
Alfuzosin
Alfuzosin, which is a racemate, is an oral quinazoline derivative which selectively blocks post-synaptic alpha1-receptors.
Tadalafil
Tadalafil is a selective, reversible inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5). When sexual stimulation causes the local release of nitric oxide, inhibition of PDE5 by tadalafil produces increased levels of cGMP in the corpus cavernosum. This results in smooth muscle relaxation and inflow of blood into the penile tissues, thereby producing an erection. Tadalafil has no effect in the treatment of erectile dysfunction in the absence of sexual stimulation. Tadalafil 5 mg - The effect of PDE5 inhibition on cGMP concentration in the corpus cavernosum is also observed in the smooth muscle of the prostate, the bladder and their vascular supply. The resulting vascular relaxation increases blood perfusion which may be the mechanism by which symptoms of benign prostatic hyperplasia are reduced. These vascular effects may be complemented by inhibition of bladder afferent nerve activity and smooth muscle relaxation of the prostate and bladder.

Pharmacodynamic effect
Alfuzosin
In vitro studies have confirmed the selectivity of alfuzosin for alpha1-adrenoreceptors located in the prostate, the trigonum of the urinary bladder and the prostatic urethra.
Tadalafil
Studies in vitro have shown that tadalafil is a selective inhibitor of PDE5. PDE5 is an enzyme found in corpus cavernosum smooth muscle, vascular and visceral smooth muscle, skeletal muscle, platelets, kidney, lung, and cerebellum. The effect of tadalafil is more potent on PDE5 than on other phosphodiesterases. Tadalafil is > 10,000-fold more potent for PDE5 than for PDE1, PDE2, and PDE4, enzymes which are found in the heart, brain, blood vessels, liver, and other organs. Tadalafil is > 10,000-fold more potent for PDE5 than for PDE3, an enzyme found in the heart and blood vessels. This selectivity for PDE5 over PDE3 is important because PDE3 is an enzyme involved in cardiac contractility. Additionally, tadalafil is approximately 700-fold more potent for PDE5 than for PDE6, an enzyme which is found in the retina and is responsible for phototransduction. Tadalafil is also > 10,000-fold more potent for PDE5 than for PDE7 through PDE10.

5.2 Pharmacokinetic properties
Absorption
Alfuzosin
The maximal plasma concentration is achieved 9 hours after administration. Studies have shown that consistent pharmacokinetic profiles are obtained when the product is administered after a meal. After the first dose (fed) the mean maximum plasma concentration was 7.72 ng/ml, AUCinf was 127 ng x h/ml (fed), and tmax was 6.69 h (fed). Under steady state conditions (fed) the mean AUC over the dosing interval (AUCτ) was 194 (SD = 75) ng x h/ml, mean Cmax was 13.6 (SD = 5.6) ng/ml and Cmin was 3.1 (SD = 1.6) ng/ml)
Tadalafil
Tadalafil is readily absorbed after oral administration and the mean maximum observed plasma concentration (Cmax) is achieved at a median time of 2 hours after dosing. Absolute bioavailability of tadalafil following oral dosing has not been determined. The rate and extent of absorption of tadalafil are not influenced by food, thus Tadalafil may be taken with or without food. The time of dosing (morning versus evening) had no clinically relevant effects on the rate and extent of absorption.

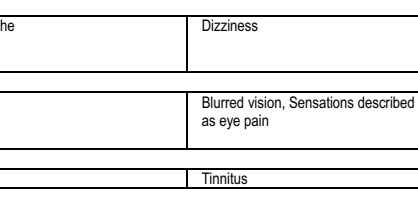
Distribution
Alfuzosin
The binding rate to plasma protein is approx. 90%. Alfuzosin's distribution volume is 2.5 l/kg in healthy volunteers. It has been shown to preferentially distribute in the prostate in comparison to plasma.
Tadalafil
The mean volume of distribution is approximately 63 l, indicating that tadalafil is distributed into tissues. At therapeutic concentrations, 94 % of tadalafil in plasma is bound to proteins. Protein binding is not affected by impaired renal function. Less than 0.0005 % of the administered dose appeared in the semen of healthy subjects.

Biotransformation
Alfuzosin
Alfuzosin is extensively metabolised in the liver (through various routes). None of the metabolites are pharmacologically active. Metabolic interactions: CYP3A4 isoform is the principal hepatic enzyme involved in the metabolism of alfuzosin.
Tadalafil
Tadalafil is predominantly metabolised by the cytochrome P450 (CYP) 3A4 isoform. The major circulating metabolite is the methylcatechol glucuronide. This metabolite is at least 13,000-fold less potent than tadalafil for PDE5. Consequently, it is not expected to be clinically active at observed metabolite concentrations.

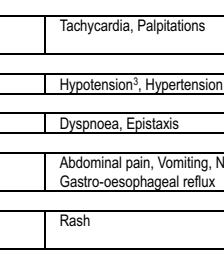
Elimination
Alfuzosin
The apparent elimination half-life is approx. 9.1 hours. Alfuzosin metabolites are eliminated via renal excretion and probably also via biliary excretion. Of an oral dose, 75-91% is excreted in the faeces, 35% in unmodified form and the rest as metabolites, which indicates some degree of biliary excretion. About 10% of the dose is excreted in the urine in its unmodified form.
Tadalafil
The mean oral clearance for tadalafil is 2.5 l/h and the mean half-life is 17.5 hours in healthy subjects. Tadalafil is excreted predominantly as inactive metabolites, mainly in the faeces (approximately 61 % of the dose) and to a lesser extent in the urine (approximately 36 % of the dose).

6.NON CLINICAL PROPERTIES
Alfuzosin
Pre-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, or reproductive toxicity
Tadalafil
Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction. There was no evidence of teratogenicity, embryotoxicity or foetotoxicity in rats or mice that received up to 1000 mg/kg/day tadalafil. In a rat prenatal and postnatal development study, the no observed effect dose was 30 mg/kg/day. In the pregnant rat the AUC for calculated free drug at this dose was approximately 18 times the human AUC at a 20 mg dose. There was no impairment of fertility in male and female rats. In dogs given tadalafil daily for 6 to 12 months at doses of 25 mg/kg/day (resulting in at least a 3-fold greater exposure [range 3.7 - 18.6] than seen in humans given a single 20 mg dose) and above, there was regression of the seminiferous tubular epithelium that resulted in a decrease in spermatogenesis in some dogs.

7. DESCRIPTION
This product (tablet) contains:alfizosin & tadalafil as active ingredient and it is indicated For the treatment of patients with Lower urinary Tract Symptoms (LUTS) associated with benign Prostatic Hyperplasia (BPH)
Alfuzosin is a monocarboxylic acid amide, a tetrahydrofuranol and a member of quinazolines. It has a role as an antineoplastic agent, an antihypertensive agent and an alpha-adrenergic antagonist.
Molecular Formula – $C_{19}H_{27}N_5O_4$
Molecular Weight – 389.4 g/mol
Chemical Structure



Tadalafil is a selective phosphodiesterase-5 inhibitor that is used in the treatment of erectile dysfunction (ED), pulmonary arterial hypertension (PAH), and benign prostatic hypertrophy.
Molecular Formula – C22H19N3O4
Molecular Weight – 389.4 g/mol
Chemical Structure



8. PHARMACEUTICAL PARTICULARS
8.1 Incompatibility
Not applicable

8.2 Shelf Life
24 months

8.3 Packaging Information
10's blister for sale & 2's blister for PS

8.4 Storage instructions
Store below 30°C.
Keep out of reach of children.

9. PATIENT COUNSELLING INFORMATION
What is Alfuzosin& tadalafil
This Alfuzosin& tadalafil is used for people who have problems with their lower urinary tract, which can cause symptoms like difficulty urinating.
This drug helps treat these symptoms when they're caused by an enlarged prostate, a condition called benign prostatic hyperplasia (BPH).

How to Take
Dosage: You should take one tablet each day, as your doctor tells you.
How to Take: Swallow the tablet with water.

When Not to Use
Do Not Use If:
You're allergic to the medication or similar drugs.
You have certain conditions like very low blood pressure, severe liver problems, or if you're taking certain other medications like nitrates.
You've recently had a heart attack, stroke, or other serious heart conditions.
Special Warnings and Precautions

Be Careful If You Have:
Severe kidney problems.
Low blood pressure or are taking medications for it.
Watch for:
Dizziness or feeling faint, especially when you start taking the medication.
If you have heart problems, talk to your doctor about using this medication safely.

Before Starting Treatment:
Your doctor will check your overall health, especially your heart, before prescribing this medication.

Be Cautious If You're Taking:
Other medications that lower blood pressure or treat erectile dysfunction.
Certain antibiotics or antifungal medications.
Always inform your doctor about all medications you're taking.

Not for Pregnant or Breastfeeding Women:
Be Aware: This medication may cause dizziness or fatigue, especially at the beginning of treatment. Be cautious when driving or operating machinery.

Side Effects:
Common Side Effects: Dizziness, headache, tiredness, visual disturbances, and nausea.
Uncommon Side Effects: Changes in heart rate, flushing, abdominal pain, and skin rash.

Overdose:
Symptoms: Too much of this medication can cause low blood pressure and rapid heart rate.
What to Do: If you take too much, seek medical help. Treatment may include fluids and medications to raise blood pressure.
Remember, always follow your doctor's instructions carefully and let them know if you experience any unusual symptoms.

10. MANUFACTURED BY
Akums Drugs & Pharmaceuticals Ltd.
At: Plot no. 26A, 27-30, Sector-8A, IIE,
SIDCUL, Ranipur, Haridwar-249403 (Uttarakhand).

DETAILS OF MARKETED BY
Dr. Reddy's Laboratories Limited,
H B No. 147, Vill. Rajgarh, Tepla- Banur Road, P.O. Tepla,
Near Shambhu Barrier, Tehsil - Rajpura, Distt. Patiala, Punjab - 140 417.

11. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE
M.L. 4/UA/LL/2014, 13.06.2023

12. DATE OF REVISION
June 2024

For further Information, please write to
Medical Information cell, Branded Formulations,
Dr. Reddy's Laboratories Ltd.,
7-1-27, Ameerpet, Hyderabad - 500016.
Toll Free No.: 1800 425 0014
email: customerservices@drreddys.com,