



Tiagra

Tadalafil 5 mg & 10 mg Tablet

Composition:

Tiagra 5 Tablet: Each film coated tablet contains Tadalafil INN 5 mg.

Tiagra 10 Tablet: Each film coated tablet contains Tadalafil INN 10 mg.

Mode of Action: The physiological mechanism responsible for penile erection during sexual stimulation is caused by increased penile blood flow resulting from the relaxation of penile arteries and corpus cavernosal smooth muscle. This response is mediated by the release of Nitric Oxide (NO) from nerve terminals and endothelial cells, which stimulates the synthesis of cGMP in smooth muscle cells. Cyclic GMP causes smooth muscle relaxation and increased blood flow into the corpus cavernosum. The inhibition of phosphodiesterase type 5 (PDE5) enhances erectile function by increasing the amount of cGMP. Studies in vitro have demonstrated that Tadalafil is a selective inhibitor of PDE5. Because sexual stimulation is required to initiate the local release of nitric oxide, the inhibition of PDE5 by Tadalafil has no effect in the absence of sexual stimulation. The effect of PDE5 inhibition on cGMP concentration in the corpus cavernosum and pulmonary arteries is also observed in the smooth muscle of the prostate, the bladder and their vascular supply thus improve the symptom of benign prostatic hyperplasia (BPH).

Indications: Tadalafil is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of: Erectile dysfunction (ED). The signs and symptoms of benign prostatic hyperplasia (BPH), ED and the signs and symptoms of BPH (ED/BPH) & Pulmonary Hypertension.

Dosage and administration: Tiagra for Use as Needed for Erectile Dysfunction: The recommended starting dose of Tadalafil for use as needed in most patients is 10 mg, taken prior to anticipated sexual activity. The dose may be increased to 20 mg or decreased to 5 mg, based on individual efficacy and tolerability. The maximum recommended dosing frequency is once per day in most patients. Tadalafil for use as needed was shown to improve erectile function compared to placebo up to 36 hours following dosing. Therefore, when advising patients on optimal use of Tadalafil, this should be taken into consideration.

Tiagra for Once Daily Use for Erectile Dysfunction: The recommended starting dose of Tadalafil for once daily use is 2.5 mg, taken at approximately the same time every day. Without regard to timing of sexual activity. The Tadalafil dose for once daily use may be increased to 5 mg, based on individual efficacy and tolerability.

Tiagra for Once Daily Use for Benign Prostatic Hyperplasia: The recommended dose of Tadalafil for once daily use is 5 mg, taken at approximately the same time every day.

Usual Adult Dose for Pulmonary Hypertension: 40 mg orally once daily, with or without food. Dividing the dose (40 mg) over the course of the day is not recommended.

Side effects: Common side effects persist or become bothersome when using Tadalafil: Flushing; headache; heartburn; mild pain in the arms, legs, or back; muscle pain; nausea; stomach upset; stuffy nose.

Precautions: Tadalafil should not be used together with nitrate medication, such as nitroglycerin (Nitro Dur, NitroLingual, Nitrostat, Transderm Nitro, and others), isosorbide dinitrate (Dilatrate, Isordil, Isochron), isosorbide mononitrate (Imdur, ISMO, Monoket), or recreational drugs such as amyl nitrate or nitrite ("poppers"). Taking Tadalafil with a nitrate medicine for chest pain or heart problems can cause a sudden and serious decrease in blood pressure, severe impairment of pulmonary or renal function; moderate impairment of hepatic function; and toxic psychosis. Use not recommended in patients with a recent MI (within 90 days) or stroke (within 6 months); uncontrolled arrhythmias, hypotension (<90/50 mm Hg systolic/diastolic BP) or uncontrolled hypertension (170/110 mm Hg systolic/diastolic BP); heart failure (>NYHA class II) in the previous 6 months; or those with unstable angina or angina occurring during sexual intercourse. Possible hypotension, particularly in patients with left-ventricular outflow obstruction (e.g., aortic stenosis, idiopathic hypertrophic subaortic stenosis) and in patients with severely impaired autonomic control of blood pressure.

Pediatric Use: Safety and efficacy not established in patients <18 years of age.

Geriatric Use: Safety and efficacy in those > 65 years of age is similar to that in younger men. Possibility exists of greater sensitivity to the drug in some geriatric individuals.

Use in Patients with Hepatic Impairment: Use not recommended in patients with severe hepatic impairment.

Use in Patients with Renal Impairment: Clearance decreased in patients with mild (Cl_{cr} 51-80 mL/minute) to severe renal insufficiency (end-stage renal disease on hemodialysis), and may result in increased adverse effects (e.g., back pain). No dosage adjustments are necessary in those with mild renal impairment. Creatinine clearance less than 30 mL/min or on hemodialysis: Tadalafil for once daily use is not recommended.

Overdosage: Single doses 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. Hemodialysis contributes negligibly to tadalafil elimination.

Drug Interactions: Tadalafil can potentiate the hypotensive effects of nitrates, alpha blockers, antihypertensives or alcohol. CYP3A4 inhibitors (e.g. ketoconazole, ritonavir) increase Tadalafil exposure. For concomitant use with potent CYP3A4 inhibitors, dose adjustment may be needed. CYP3A4 inducers (e.g. rifampin) decrease Tadalafil exposure.

Contraindications: Administration of Tadalafil to patients who are using any form of organic nitrate, either regularly and/or intermittently, is contraindicated. In clinical pharmacology studies, Tadalafil was shown to potentiate the hypotensive effect of nitrates.

Storage: Do not store above 30°C. Protect from light. Keep out of reach of children.

Packaging:

Tiagra 5 Tablet: Each box contains 8's tablets in blister pack.

Tiagra 10 Tablet: Each box contains 8's tablets in blister pack.

Manufactured by



Ziska Pharmaceuticals Ltd.

Kaliakoir, Gazipur, Bangladesh