

COMPOSITION

Each film coated tablet contains Tadalafil BP 10 mg.

PHARMACOLOGY

Cialix (Tadalafil) is a selective phosphodiesterase type 5 (PDE5) inhibitor. Inhibition of PDE5 increases cGMP in smooth muscle cells. cGMP causes smooth muscle relaxation and increased blood flow into the corpus cavernosum, causing penile erection. PDE5 also is present in smooth muscles of the prostate and bladder wall. Inhibiting PDE5 increases cGMP concentrations leading to relaxation of smooth muscle in the prostate and bladder. Smooth muscle relaxation may improve blood flow to the urinary tract and widen the opening of the bladder neck, resulting in improved voiding.

INDICATIONS

- Erectile Dysfunction (ED)
- Benign Prostatic Hyperplasia (BPH)
- Both Erectile Dysfunction and signs and symptoms of Benign Prostatic Hyperplasia

DOSAGE AND ADMINISTRATION

Erectile Dysfunction: For most patients the recommended starting dose is 10 mg. The dose may be increased to 20 mg or decreased to 5 mg based on requirement. The maximum dosing frequency is once daily. **Cialix** is effective for up to 36 hours.

Benign prostatic hyperplasia: The recommended dose is 5 mg taken at the same time every day.

Combined Erectile Dysfunction and Benign prostatic hyperplasia: The recommended dose is 5 mg at the same time every day.

CONTRAINDICATIONS

- Use of Nitrates (for example, Nitroglycerine, Isosorbide): **Cialix** may increase hypotensive effects of Nitrates
- Hypersensitivity reactions to Tadalafil

WARNING AND PRECAUTION

Angina, renal impairment, hepatic impairment, bleeding concomitant with Nitrates, Alpha Blockers, Alcohol, CYP3A4 Inhibitors (for example, Ritonavir, Ketoconazole, Itraconazole), other PDE5 inhibitors precaution should be taken in all these conditions.

SIDE EFFECTS

Headache, Dyspepsia, Back pain, Myalgia, Nasal pharyngitis, Nasal congestion are common side effects. Change in Color Vision, Sudden vision loss, Hearing loss, Stevens-Johnson Syndrome, Exfoliative dermatitis, Angina, Stroke, Myocardial infarction, Severe hypotension, Tachycardia may also occur rarely.

USE IN PREGNANCY AND LACTATION

Tadalafil is not indicated for use in females.

USE IN CHILDREN AND ADOLESCENTS

Tadalafil is not indicated for use in paediatric patients. Safety and efficacy of Tadalafil in patients below the age of 18 years has not been established.

DRUG INTERACTIONS

May interact with Nitrates for example, Isosorbide, Nitroglycerin, Alpha adrenergic blockers, Antihypertensives, Alcohol, Antacids (magnesium hydroxide/aluminum hydroxide), Ketoconazole, Ritonavir, Erythromycin, Itraconazole, Grapefruit juice, other HIV protease inhibitors, Rifampin, Carbamazepine, Phenytoin & Phenobarbital.

OVERDOSAGE

In cases of overdose, standard supportive measures should be adopted as required.

STORAGE

Store below 30°C temperature in a cool & dry place. Keep out of the reach of children.

HOW SUPPLIED

Each box contains 4 tablets in Alu-PVDC blister pack.