

Cialis[®]

Tadalafil
10 mg Tablet

Cialis[®] (Tadalafil) is a selective phosphodiesterase type 5 (PDE5) inhibitor. Inhibition of PDE5 increases cGMP in smooth muscle cells. Cyclic GMP 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.

COMPOSITION

Each film coated tablet contains Tadalafil INN 10 mg.

INDICATION

- 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. **Cialis[®]** 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.

SIDE EFFECT

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

PRECAUTION

Angina, nitrates, alpha blockers, renal impairment, hepatic impairment, alcohol, CYP3A4 inhibitors (for example, ritonavir, ketoconazole, itraconazole), other PDE5 inhibitors, bleeding - precaution should be taken in all these conditions.

CONTRAINDICATION

- Use of nitrates (for example, nitroglycerine, isosorbide): **Cialis[®]** may increase hypotensive effects of nitrates.
- Hypersensitivity reactions to tadalafil.

DRUG INTERACTION

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.

USE IN PREGNANCY & LACTATION

Tadalafil has been assigned to pregnancy category B by the USFDA. Tadalafil is only recommended for use during pregnancy when benefit outweighs risk. There are no data on the excretion of tadalafil in human milk. Caution should be used when administering tadalafil to nursing women.

STORAGE CONDITION

Keep in a dry place away from light and heat. Keep out of reach of children.

HOW SUPPLIED

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

Manufactured by:

NIPRO JMI Pharma Ltd.
Comilla, Bangladesh.