

Tadalafil

Tadalafil INN

Composition

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

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

Pharmacology

When sexual stimulation causes the local release of nitric oxide in the corpus cavernosum, nitric oxide then activates the enzyme guanylyl cyclase, which results in increased levels of cGMP. The increased levels of cGMP in the corpus cavernosum produce smooth muscle relaxation and inflow of blood into the penile tissues, thereby producing an erection. PDE₅ degrades cGMP in the corpus cavernosum and the inhibition of PDE₅ by Tadalafil maintains increased levels of cGMP in the corpus cavernosum. Tadalafil has no effect on penile blood flow in the absence of sexual stimulation.

Indications

Erectile Dysfunction

Tadalafil is indicated for the treatment of erectile dysfunction (ED).

Benign Prostatic Hyperplasia

Tadalafil is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).

Erectile Dysfunction and Benign Prostatic Hyperplasia

Tadalafil is indicated for the treatment of ED and the signs and symptoms of BPH (ED/BPH).

Dosage and Administration

Erectile Dysfunction

Tadalafil 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 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.

Tadalafil 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.

Tadalafil for Once Daily Use for Erectile Dysfunction and Benign Prostatic Hyperplasia:

The recommended dose of Tadalafil for once daily use is 5 mg, taken at approximately the same time every day, without regard to timing of sexual activity.

Renal Insufficiency:

For use as needed:

- Mild (creatinine clearance 51 to 80 mL/min): No dose adjustment is required.
- Moderate (creatinine clearance 31 to 50 mL/min): A starting dose of 5 mg not more than once per day is recommended and the maximum dose should be limited to 10 mg not more than once in every 48 hours.
- Severe (creatinine clearance < 30 mL/min and on hemodialysis): The maximum recommended dose is 5 mg not more than once in every 72 hours.

For once daily use:

- Mild (creatinine clearance 51 to 80 mL/min): No dose adjustment is required.
- Moderate (creatinine clearance 31 to 50 mL/min): No dose adjustment is required.
- Severe (creatinine clearance < 30 mL/min and on hemodialysis): Tadalafil for once daily use is not recommended.

Hepatic Impairment, For use as needed:

- Mild or moderate: The dose should not exceed 10 mg once per day.
- Severe: Not recommended.

For once daily use:

- Mild or moderate: Tadalafil for once daily use has not been extensively evaluated in patients with hepatic insufficiency. Therefore, caution is advised if Tadalafil for once daily is prescribed to these patients.
- Severe: Not recommended.

Geriatrics:

No dose adjustment is required in patients >65 years of age.

Use with Food:

Tadalafil may be taken without regard to food.

Contraindications:

Nitrates:

Administration of Tadalafil to patient 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.

Hypersensitivity Reactions:

Tadalafil is contraindicated in patients with a known serious hypersensitivity to Tadalafil. Hypersensitivity reactions have been reported, including Stevens-Johnson syndrome and exfoliative dermatitis.

Side Effects

Body as a whole: Hypersensitivity reactions including rash, urticaria, facial edema, Stevens-Johnson syndrome and exfoliative dermatitis.

Cardiovascular and cerebrovascular: Serious cardiovascular events, including myocardial infarction, sudden cardiac death, unstable angina pectoris, ventricular arrhythmia, stroke, transient ischemic attacks, chest pain, palpitations and tachycardia may occur. Most of the patients in whom these events have been reported had pre-existing cardiovascular risk factors. Hypotension (more commonly reported when Tadalafil is given to patients who are already taking antihypertensive agents), hypertension and syncope.

Skin and subcutaneous tissues: Hyperhidrosis (sweating).

Gastrointestinal: Abdominal pain and gastroesophageal reflux.

Nervous system: Migraine, transient global amnesia.

Respiratory system: Epistaxis (nose bleed).

Special senses: Blurred vision, nonarteritic anterior ischemic optic neuropathy, retinal vein occlusion, visual field defect.

Otologic: Cases of sudden decrease or loss of hearing have been reported.

Pregnancy & Lactation:

It is not indicated for use in newborn, children or women.

Precautions

Evaluation of erectile dysfunction and BPH should include an appropriate medical assessment to identify potential underlying causes, as well as treatment options. Before prescribing Tadalafil, it is important to note the following: cardiovascular status of the patient, interaction with other medicines (Nitrates, alpha-blocker, anti-hypertensive and potent inhibitors of CYP3A4) and with substantial consumption of alcohol, sudden loss of vision, sudden hearing loss, renal insufficiency & hepatic impairment.

Over Dosage

Adverse events were similar to those seen at lower doses. In case of overdose, standard supportive measure should be adopted as required.

Storage

Store below 30°C. Protect from light and moisture. Keep out of reach of children.

How Supplied

Tadalafil 5 mg Tablet: Each box contains 1X4's tablets in Alu-PVC blister pack.

Tadalafil 10 mg Tablet: Each box contains 1X4's tablets in Alu-PVC blister pack.

Manufactured by:

