Penfil

Tadalafil

Composition

Penfil 10 mg Tablet: Each film coated tablet contains Tadalafil INN 10 mg
Penfil 20 mg Tablet: Each film coated tablet contains Tadalafil INN 20 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 tissue, thereby producing an erection. PDE5 degrades cGMP in the corpus cavernosum. Tadalafil has no effect on penile blood flow in the absence of sexual stimulation.

Indication

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

Dosage & Administration: Erectile Dysfunction

For Use as Needed:

The recommended starting dose of Penfil 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.

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

Renal Insufficiency: For Use as Needed

Mild (creatinine clearance 51 to 80 ml/min) : No dose adjustment is required. Moderate (Creatine 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 10mg 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 (creatine 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): Penfil 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 use is prescribed to these patients.

Severe: Not recommended.

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

Use With Food: Penfil may be taken without regard to food

Contra-indications

Nitrates: 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.

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 sysem : Migraine, transient global amnesia.

Respiratory system : Epistaxis (Nose bleed)

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

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.

Overdosage

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.

Commercial Pack

Penfil 10 mg Tablet : Each box contains 4 tablets.
Penfil 20 mg Tablet : Each box contains 4 tablets.

Manufactured by

BIOPHARMA
LIMITED
A-116, BSCIC, Industrial Estate
TONGI, GAZIPUR, BANGLADESH

For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.