

Vgofil[®]

Tadalafil

COMPOSITION :

Vgofil[®] 10 Tablet: Each film coated tablet contains Tadalafil USP 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.

INDICATION :

Vgofil[®] is indicated for the treatment of erectile dysfunction (ED).

Vgofil[®] is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).

Vgofil[®] is indicated for the treatment of erectile dysfunction and the signs of benign prostatic hyperplasia (ED/BPH).

DOSAGE & ADMINISTRATION :

Erectile Dysfunction:

For Use as Needed:

- The recommended starting dose of Vgofil[®] 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 Vgofil[®] for once daily use is 2.5 mg, taken at approximately the same time every day, without regard to timing of sexual activity.
- The Vgofil[®] dose for once daily use may be increased to 5 mg, based on individual efficacy and tolerability.

Patients with BPH or with ED and BPH:

Vgofil[®] for once daily use for BPH: The recommended dose of Vgofil[®] for once daily use is 5 mg, taken at approximately the same time every day

Vgofil[®] for once daily use for ED+BPH: The recommended dose of Vgofil[®] 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): Vgofil[®] 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: Vgofil[®] may be taken without regard to food.

CONTRAINDICATIONS :

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.

WARNINGS AND PRECAUTIONS :

Cardiovascular: Physicians should consider the cardiovascular status of their patients, since there is a degree of cardiac risk associated with sexual activity. Potential for drug interactions when taking tadalafil for once daily use physicians should be aware that tadalafil for once daily use provides continuous plasma tadalafil levels and should consider this when evaluating the potential for interactions with medications (e.g., nitrates, alpha-blockers, anti-hypertensives and potent inhibitors of CYP3A4).

Prolonged Erection: There have been rare reports of prolonged erections greater than 4 hours and priapism (painful erections greater than 6 hours in duration) for this class of compounds. Priapism, if not treated promptly, can result in irreversible damage to the erectile tissue. Patients who have an erection lasting greater than 4 hours, whether painful or not, should seek emergency medical attention. Tadalafil should be used with caution in patients who have conditions that might predispose them to priapism (such as sickle cell anemia, multiple myeloma, or leukemia), or in patients with anatomical deformation of the penis (such as angulation, cavernosal fibrosis, or Peyronie's disease).

Eye & Sudden Hearing Loss: Physicians should advise patients to stop use of all PDE5 inhibitors, including tadalafil, and seek medical attention in the event of a sudden loss of vision in one or both eyes & sudden decrease or loss of hearing.

Alpha blockers and Antihypertensives: Physicians should discuss with patients the potential for tadalafil to augment the blood-pressure-lowering effect of alpha blockers and antihypertensive medications. Caution is advised when PDE5 inhibitors are coadministered with alpha blockers. Renal Insufficiency, Hepatic Impairment, Consumption of alcohol.

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.

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 in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

Packing :

Vgofil[®] 10 Tablet: Each box contains 1 X 10's Tablets in Alu-PVC blister pack.



Manufactured by

Team Pharmaceuticals Ltd.

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