

For the use only of a registered Medical Practitioner or a Hospital or a Laboratory

Tadalafil Tablets AEROLAFIL™ 20

COMPOSITION:

Each Film Coated Tablets Contains:-
Tadalafil BP..... 20 mg
Excipients q.s

Colour : yellow Oxide of Iron.

1. Description: -Tadalafil- Tadalafil helps men with erectile dysfunction (ED). When taken as needed for ED, one dose can work up to 36 hours. It can also treat signs/symptoms of benign prostatic hyperplasia. Tadalafil is a prescription medicine used to treat impotence, known medically as erectile dysfunction (ED), and symptoms of enlarged prostate (benign prostatic hyperplasia, or BPH). It is also used to improve the ability to exercise in people with pulmonary arterial hypertension. Tadalafil is in a group of medications called phosphodiesterase 5 (PDE5) inhibitors. It works by increasing blood flow to the penis during sexual stimulation. It may also relax the prostate and bladder. Tadalafil comes in tablet form and is either taken one time before you expect to have sexual activity, or at a lower dose, once daily. Common side effects include headache, indigestion, back pain, and facial flushing. Do not take tadalafil if you are taking other medications called "nitrates."

2. Indication and usage: -Tadalafil Uses -Tadalafil is a prescription medicine used to treat impotence, known medically as erectile dysfunction (ED), and symptoms of enlarged prostate (benign prostatic hyperplasia, or BPH). It is also used to improve the ability to exercise in people with pulmonary arterial hypertension, or PAH. PAH is high blood pressure in the vessels carrying blood to the lungs, causing shortness of breath, dizziness, and tiredness

This medication may be prescribed for other uses. Ask your doctor or pharmacist for more information.

3. Dosage and Administration: -Tadalafil Dosage : Take tadalafil exactly as prescribed by your doctor. Follow the directions on your prescription label carefully.

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 use as needed was shown to improve erectile function compared to placebo up to 36 hours following dosing. Therefore, when advising patients on optimal use of tadalafil, this should be taken into consideration.

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.

Tadalafil for use in PAH:

-The dose for treating PAH is 40 mg once daily, with or without food.

-Dividing the dose over the course of the day is not recommended. (2.1)

-Use with ritonavir requires dosage adjustments.

Tadalafil Overdose

If you take too much this medication, call your healthcare provider or local Poison Control Center, or seek emergency medical attention right away.

If this medication is administered by a healthcare provider in a medical setting, it is unlikely that an overdose will occur. However, if overdose is suspected, seek emergency medical attention. Route of administration

4. Contraindication: -Tadalafil : Administration of CIALIS to patients who are using any form of organic nitrate, either regularly and/or intermittently, is contraindicated. In clinical pharmacology studies, CIALIS was shown to potentiate the hypotensive effect of nitrates. Hypersensitivity Reactions -CIALIS is contraindicated in patients with a known serious hypersensitivity to tadalafil (CIALIS or AEROLAFIL™). Hypersensitivity reactions have been reported, including *Stevens-Johnson syndrome* and exfoliative *dermatitis*. Concomitant Guanylate Cyclase (GC) Stimulators

Do not use CIALIS in patients who are using a GC stimulator, such as riociguat. PDE5 inhibitors, including CIALIS, may affect the effects of GC stimulators.

5. Warning and Precautions: - Tadalafil :- Physicians should consider the *cardiovascular* status of their patients, since there is a degree of cardiac risk associated with sexual activity. Therefore, treatments for erectile dysfunction, including CIALIS, should not be used in men for whom sexual activity is inadvisable as a result of their underlying cardiovascular status. Patients who experience symptoms upon initiation of sexual activity should be advised to refrain from further sexual activity and seek immediate medical attention.

6. Side effects: Tadalafil :-Some of the serious side-effects of the drug which demand immediate medical attention are:

- Blurred vision
- Chest pain or discomfort
- Irregular or fast heart beat
- Hearing loss
- Swelling in hands, feet or ankles
- Shortness of breath

7. Drug interaction: Tadalafil :-Potential For Pharmacodynamic Interactions With CIALIS.Nitrates: Administration of CIALIS to patients who are using any form of organic nitrate, is contraindicated. In clinical pharmacology studies, CIALIS was shown to potentiate the *hypotensive* effect of nitrates. In a patient who has taken CIALIS, where nitrate administration is deemed medically necessary in a life-threatening situation, at least 48 hours should elapse after the last dose of CIALIS before nitrate administration is considered

8. Pharmacology: Tadalafil :-Penile erection during sexual stimulation is caused by increased penile blood flow resulting from the relaxation of penile arteries and corpus cavernosum smooth muscle. This response is mediated by the release of nitric oxide (NO) from nerve terminals and endothelial cells, which stimulates the synthesis of cGMP in smooth muscle cells. Cyclic GMP causes smooth muscle relaxation and increased blood flow into the corpus cavernosum. The inhibition of phosphodiesterase type 5 (PDE5) enhances erectile function by increasing the amount of cGMP. Tadalafil inhibits PDE5. Because sexual stimulation is required to initiate the local release of nitric oxide, the inhibition of PDE5 by tadalafil has no effect in the absence of sexual stimulation.

9. Pharmacokinetics properties: -Tadalafil 20 mg administered to healthy male subjects produced no significant difference compared to placebo in supine systolic and diastolic blood pressure (difference in the mean maximal decrease of 1.6/0.8 mm Hg, respectively) and in standing systolic and diastolic blood pressure (difference in the mean maximal decrease of 0.2/4.6 mm Hg, respectively). In addition, there was no significant effect on heart rate.

10. How to supplied : 10 x 10 Tablets.

SHELF LIFE: Refer to carton & strip.

Special precautions for storage:

Store in a cool dry & dark place.

Protect from light & moisture.

Keep all medicines out of reach of children.

Número de registro:
Código neutral: HP/Drugs/09/92

Manufactured for: Area Biotech Pvt.Ltd.
Marketed and Exported By:
AREA IMPORTERS & EXPORTERS PVT. LTD.
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