

PRINT - F/B

104 mm x 133 mm

SILDENAFIL CITRATE

ANEXXX

50 mg & 100 mg Film-Coated Tablet
PDE5 Inhibitor

Formulation:

Each film-coated tablet contains:
Sildenafil Citrate
Eq. to Sildenafil 50 mg
Excipients q.s.
Colour: Indigo Carmine

Each film-coated tablet contains:
Sildenafil Citrate
Eq. to Sildenafil 100 mg
Excipients q.s.
Colour: Indigo Carmine

Sildenafil Citrate tablet is an oral therapy for erectile dysfunction. It contains the citrate salt of sildenafil, a selective inhibitor of cyclic guanosine mono phosphate (cGMP) specific phosphodiesterase type 5 (PDE)

Indications:

Sildenafil Citrate is a tablet used to treat erectile in men. It can help many men who have erectile dysfunction get and keep an erection when they become sexually excited (stimulated).

Contraindications:

Sildenafil Citrate tablet is contraindicated in patients suffering from heart problems (e.g., angina, chest pain, heart failure, irregular heartbeat, low or high blood pressure). Sildenafil Citrate is contraindicated in patients suffering from severe vision loss, kidney problems, liver problems, blood problems, including sickle cell anemia or leukemia and are allergic to sildenafil or any of the other ingredients of Sildenafil Citrate tablets, deformed penis, have stomach ulcers or bleeding problems.

Adverse Effects:

The most common adverse effects of Sildenafil Citrate are headache, facial flushing, and upset stomach. Less commonly, bluish vision, blurred vision, or sensitivity to light may briefly occur. In rare instances, men taking PDE inhibitors reported a sudden decrease or loss of vision. It is not possible to determine whether these events are related directly to these medicines or to other factors.

Precautions:

Sildenafil Citrate must be used by men who are taking medicines that contain nitrates of any kind, at any time like nitroglycerin. If Sildenafil Citrate is taken with any drug belonging to the nitrate group, blood pressure could suddenly drop to an unsafe or life threatening level. The concomitant administration of the protease inhibitor ritonavir (a highly potent CYP3A4 inhibitor) substantially increases serum concentrations of sildenafil, therefore co-administration with Sildenafil Citrate is not recommended. It has vasodilator properties, resulting in mild and transient decreases in blood pressure. Prior to prescribing Sildenafil Citrate physicians should carefully consider whether their patients with certain underlying conditions could adversely affected by such vasodilatory effects, caution is advised when a phosphodiesterase type 5 (PDE) inhibitor is co-administered with alpha blocker, PDE inhibitors, including sildenafil and alpha adrenergic blocking agent are both vasodilators with blood pressure lowering effects. When vasodilators are used in combination, an additive effect on blood pressure may be anticipated. It should be used with caution in patients with anatomical deformation of the penis. In humans, sildenafil has no effect on bleeding time when alone or with aspirin.

Drug Interaction:

In patients suffering from hypertension, the concomitant use of Vitamin K antagonist and sildenafil resulted in a greater incidence of reports of bleeding (primary epistaxis) versus placebo. Nitrate containing drugs are contraindicated with Sildenafil Citrate.

Overdosage:

In case of accidental overdose, contact a doctor immediately. In studies with healthy volunteers taking single doses up to 800mg. Adverse events were similar to those seen at lower doses but rates are increased. Volunteers of single doses up to 800mg, adverse events were similar to those seen at lower doses but rates are increased.

In case of overdose, standard supportive measures should be adopted as required. Renal dialysis is not expected to accelerate clearance as sildenafil is highly bound to plasma proteins and is not eliminated in urine.

Dosage:

Sildenafil Citrate is a phosphodiesterase type-5 inhibitor used in the management of erectile dysfunction and pulmonary arterial hypertension.

In erectile dysfunction the usual dose is equivalent to sildenafil 50 mg about one hour before sexual intercourse. The dose may be increased or decreased depending on response. The maximum recommended dose is 100 mg, and sildenafil citrate should not be taken more than once in 24 hours.

In patients stabilised on alpha blocker therapy, an initial dose of sildenafil 25mg should be considered.

To improve exercise ability in pulmonary arterial hypertension, Sildenafil Citrate clearance is given orally in a dose of 20 mg three times daily.

Administration in hepatic impairment. Sildenafil Citrate clearance is reduced in patients with hepatic impairment.

Erectile dysfunction. Sildenafil Citrate, an inhibitor of phosphodiesterase type-5, is used as an oral therapy for erectile dysfunction. It is effective in erectile dysfunction of psychogenic causes and organic causes such as diabetes mellitus, spinal-cord injury, and prostatectomy.

Storage: Store at temperatures not exceeding 30°C. Protect from light.

Availability: Aluminium/PVC blister pack x 4 tablets (Box of 4 Tablets)

Caution: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

ADR Statement: For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

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