

COMPOSITION

Each film coated tablet contains Sildenafil Citrate BP equivalent to Sildenafil 50 mg.

PHARMACOLOGY

Danafil (Sildenafil) is a selective inhibitor of cyclic Guanosine Monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5) used for treatment of erectile dysfunction. Danafil (Sildenafil) enhances the effect of nitric oxide (NO) by inhibiting phosphodiesterase type 5 (PDE5), which is responsible for degradation of cGMP in the corpus cavernosum that results in smooth muscle relaxation and inflow of blood to the corpus cavernosum.

INDICATIONS

Danafil (Sildenafil) is indicated for the treatment of erectile dysfunction.

DOSAGE AND ADMINISTRATION

The recommended dose of Sildenafil is 50 mg taken approximately 1 hour before sexual activity. However, Sildenafil may be taken anywhere from half an hour to 4 hours before sexual activity. Based on effectiveness and toleration, the dose may be increased to a maximum 100 mg or decreased to 25 mg. The maximum recommended dosing frequency is once per day.

CONTRAINDICATIONS

Sildenafil is contraindicated in patient with hypersensitivity to any component of this medication. Sildenafil potentiates the hypotensive effects of nitrates, so it is contraindicated in patients who are using organic nitrates, either regularly or intermittently.

WARNING & PRECAUTION

Caution should be exercised if patients have any allergies to any other medicines or any other substances such as foods, preservatives or dyes, heart or blood vessel problems, sudden loss of eyesight in one or both eyes. Caution should be taken if patients have any of the following medical conditions such as diabetes, kidney or liver problems, leukaemia, multiple myeloma, any disease or deformity of penis, any bleeding disorder such as haemophilia, stomach ulcer, sickle cell anaemia, color vision problems, sudden decrease or loss of hearing or receiving any other treatment for impotence.

SIDE EFFECTS

The adverse effects treated with Sildenafil are headache, flushing, dyspepsia, nasal congestion, urinary tract infection, abnormal vision, diarrhea, dizziness and rash.

USE IN PREGNANCY AND LACTATION

Sildenafil is not indicated for use in females.

USE IN CHILDREN AND ADOLESCENTS

Sildenafil is not indicated for use in paediatric patients. Safety and efficacy of Sildenafil in patients below the age of 18 years has not been established.

DRUG INTERACTIONS

Concomitant use of Sildenafil with organic nitrates for angina may cause hypotension. Cimetidine, a medicine used to treat gastric ulcers, some antibiotics including Erythromycin and Rifampicin, some protease inhibitors such as Ritonavir and Saquinavir for the treatment of HIV infection may increase the plasma concentration of Sildenafil. Some medicines used to treat fungal infections including Ketoconazole and Itraconazole may reduce the clearance of Sildenafil.

OVERDOSAGE

In cases of overdose, standard supportive measures should be adopted as required.

STORAGE

Store below 30°C temperature in a cool & dry place. Keep out of the reach of children.

HOW SUPPLIED

Each box contains 4 tablets in Alu-PVDC blister pack.



Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.