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# SDF®

Sildenafil (As citrate)

F.C. Tablets

## Category:

Impotence therapy agent

## Indications:

*Erectile dysfunction:* SDF® is indicated to facilitate erections in men with erectile dysfunction.

## Pharmacology/Pharmacokinetics:

SDF® (sildenafil citrate) is a selective inhibitor of phosphodiesterase type 5 (PDE5), an enzyme responsible for degrading cyclic guanosine monophosphate (cGMP) in the corpus cavernosum; Rapidly absorbed; absolute bioavailability is approximately 40%. A high-fat meal reduces absorption as shown by reducing the maximum plasma concentration (C max) by 29% and delaying time to peak concentration (T max) by 60 minutes; Protein binding 96%; Hepatic metabolism, via cytochrome P450 (CYP) 3A4 (major route) and CYP2C9 (minor route) with Half-life of about 4 hours; it has onset of action of about 0.5 hour after administration. Duration of action is up to 4 hours, but with less response than that seen at 2 hours.

Eliminate fecal (80% of the administered dose as metabolites); urinary (13% of the administered dose as metabolites).

## Pregnancy & Breast-feeding:

FDA Pregnancy Category B; Problems in nursing mothers have not been documented.

## Drug interactions and/or related problems:

Antihypertensive medications (such as amlodipine); Enzyme inhibitors, hepatic, cytochrome P450 (CYP) 3A4 including Cimetidine, Erythromycin, Itraconazole, Ketoconazole; Enzyme inducers, hepatic, cytochrome P450 (CYP) 3A4, including rifampin; Nitrates, including nitroglycerin (SDF® potentiates the hypotensive effect of nitrates; concomitant use is contraindicated).

## Medical considerations/Contraindications:

*Risk-benefit should be considered when the following medical problems exist*

Abnormalities of the penis ( such as: Anatomical deformity, Angulation of the penis, Cavernosal Peyronie's disease and fibrosis Hypospadia), Bleeding disorders (including peptic ulcer); Cardiac failure ( Coronary artery disease causing unstable angina or Hypertension resulting in a blood pressure > 170/100 mm Hg or Hypotension resulting in a blood pressure < 90/50 mm Hg or Life-threatening arrhythmia, history of (within the previous 6 months) or Myocardial infarction, history of (within the previous 6 months) or Stroke, history of (within the previous 6 months).

Cirrhosis or Hepatic function impairment; Leukemia or Myeloma, multiple or Polycythemia or Priapism, history of or Sickle cell disease or Thrombocythemia; Renal function impairment; Retinitis pigmentosa; Sensitivity to SDF®.

## Side/Adverse Effects:

*Those indicating need for medical attention*

Incidence less frequent, 2 to 3% Abnormal vision, including blurred vision; color change perception or sensitivity to light; dizziness urinary tract infection or cystitis.

*Incidence rare:* Hematuria; ophthalmic effects, such as diplopia; increased intraocular pressure; paramacular edema; redness, burning or swelling of the eye; retinal vascular disease or bleeding; vision loss, temporary or vitreous detachment or traction; prolonged erection; priapism; Allergic reaction, anemia or asthenia; arthrosis; arthritis; gout or hyperuricemia; synovitis or tenosynovitis; tendon rupture, breast enlargement; cardiovascular effects, such as angina pectoris; AV block; cardiac arrest or sudden cardiac death; cerebral thrombosis; cerebrovascular hemorrhage; hypertension; hypotension, including orthostatic hypotension; migraine headache; myocardial ischemia, myocardial infarction or transient ischemic attack; palpitation; syncope; tachycardia; and ventricular arrhythmia; chills; deafness; edema; hyperglycemia; or hypoglycemia reaction; hypernatremia; myasthenia; ophthalmic effects, such as cataracts; conjunctivitis; dry eyes; eye hemorrhage; and mydriasis; shock; skin effects, such as contact dermatitis; pruritus or urticaria; exfoliative dermatitis; herpes simplex and skin ulcers. *Those indicating need for medical attention only if they continue or are bothersome*

Incidence more frequent: Dyspepsia 7%; flushing 10%; headache 16%; nasal congestion 4%.

Incidence less frequent: Diarrhea.

Incidence rare: Anxiety.

## Overdose:

Contact a poison control center.

## Dosing:

*Usual adult dose*

Erectile dysfunction

Oral, 50 mg (base) one hour (range, one half to four hours) before sexual intercourse once a day if needed. As tolerated, subsequent doses may be increased to 100 mg or decreased to 25 mg once a day.

*Usual adult prescribing limits*

100 mg once a day.

*Usual geriatric dose*

Erectile dysfunction

Oral, 25 mg (base) one hour (range, one half to four hours) before sexual intercourse once a day if needed. As tolerated, subsequent doses may be increased.

## How supplied:

50 and 100mg film coated scored tablets, two blisters of 4's in a folding box with a insert leaflet.

## Storage:

Storage below 30 °C, protect from direct sunlight and moisture.



Manufactured by Marham Daru Co.  
Tehran-Iran



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