

Composition : Charm-25: Each film coated tablet contains Sildenafil 25 mg as Sildenafil Citrate USP.

Charm-50: Each film coated tablet contains Sildenafil 50 mg as Sildenafil Citrate USP.

Charm-100: Each film coated tablet contains Sildenafil 100 mg as Sildenafil Citrate USP.

Pharmacology : Sildenafil Citrate, an oral therapy for erectile dysfunction, is the citrate salt of Sildenafil, a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5). It is rapidly absorbed after oral administration, with a mean absolute bioavailability of 41% (range 25-63%). It is rapidly absorbed. Maximum observed plasma concentrations are reached within 30 to 120 minutes (median 60 minutes) of oral dosing in the fasted state. Sildenafil is cleared predominantly by the CYP3A4 (major route) and CYP2C9 (minor route) hepatic microsomal isoenzymes. The major circulating metabolite results from N-desmethylation of Sildenafil, and is itself further metabolized. After either oral or intravenous administration, Sildenafil is excreted as metabolites predominantly in the feces (approximately 80% of administered oral dose) and to a lesser extent in the urine (approximately 13% of the administered oral dose).

Indications : It is indicated for the treatment of erectile dysfunction.

Dosage and administration : For most patients, the recommended dose is 50 mg taken, as needed, approximately 1 hour before sexual activity. However, it may be taken anywhere from 30 minutes to 4 hours before sexual activity. The maximum recommended dosing frequency is once per day. Based on effectiveness and toleration, the dose may be increased to a maximum recommended dose of 100 mg or decreased to 25 mg. It may be taken with or without food. Age >65, hepatic impairment and severe renal impairment are associated with increased plasma levels of Sildenafil. A starting oral dose of 25mg should be considered in those patients. Or, as directed by the registered physician.

Contraindication : It is contraindicated in patients who are hypersensitive to any component of this product. Sildenafil potentiates the hypotensive effects of Nitrates, so it is contraindicated in patients who are using organic Nitrates, either regularly or intermittently.

Precautions : Caution should be exercised when using Sildenafil in patients with cardiovascular disease, Prolonged erection and priapism, Effects

Charm Tablet



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on the eye, Hearing loss, Hypotension when co-administered with Alpha- blockers or Anti-hypertensives, Adverse reactions with the concomitant use of Ritonavir, Combination with other PDE5 inhibitors or other erectile dysfunction therapies, Effects on bleeding.

Side effects : The most common side effects are headache, flushing, dyspepsia, abnormal vision, nasal congestion, back pain, myalgia, nausea, dizziness, and rash.

Use in pregnancy and lactation : Pregnancy Category B. It is not indicated for use in women. There are no adequate and well-controlled studies of Sildenafil in pregnant women.

Use in child : It is not indicated for use in pediatric patients. The safety and effectiveness of Sildenafil in pediatric patients have 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.

Overdose : In cases 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 it is not eliminated in the urine.

Storage : Store below 30°C in a dry place, away from sunlight and keep out of reach of children.

Packing : Charm-25: Each box contains 4 tablets in a blister pack. □

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Charm-100: Each box contains 4 tablets in a blister pack.