

**Composition : Silofast-4 :** Each capsule contains Silodosin INN 4 mg.

**Silofast-8 :** Each capsule contains Silodosin INN 8 mg.

**Pharmacology :** Silodosin is a selective antagonist of post-synaptic alpha-1-adrenoreceptors, which are located in the human prostate, bladder base, bladder neck, prostatic capsule and prostatic urethra. Blockade of these alpha-1 adrenoreceptors can cause smooth muscle in these tissues to relax, resulting in an improvement in urine flow and a reduction in BPH symptoms.

**Indications :** Silodosin is a selective alpha-1 adrenergic receptor antagonist, is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).

**Dosage and administration :** 8 mg capsules taken orally once daily with a meal. 4 mg capsules taken orally once daily with a meal for those with moderate renal impairment [Creatinine Clearance (CCr) 30-50 mL/min]. Or, as directed by the registered physician.

**Side effects :** Most common adverse reactions are retrograde ejaculation, dizziness, diarrhea, orthostatic hypotension, headache, nasopharyngitis, and nasal congestion.

**Contraindication :** Silodosin is contraindicated in patients with hypersensitivity to Silodosin or any other component of this medication. Patients with severe renal impairment [Creatinine Clearance (CCr) < 30 mL/min]. Patients with severe hepatic impairment (Child-Pugh score > 10). Concomitant administration with strong Cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ketoconazole, clarithromycin, itraconazole, ritonavir).

**Use in pregnancy and lactation :**

## Silofast Capsule



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Silodosin is not indicated for use in women.

**Drug interactions :** Strong P-glycoprotein inhibitors (e.g., cyclosporine): Co-administration may increase plasma silodosin concentration. Concomitant use of PDE5 inhibitors with alpha-blockers including Silodosin can potentially cause symptomatic hypotension.

**Precautions :** Postural hypotension, with or without symptoms (e.g., dizziness), may develop when beginning Silodosin treatment. It should not be used in combination with other alpha-blockers. Inform patients planning cataract surgery to notify their ophthalmologist that they are taking Silodosin because of the possibility of Intraoperative Floppy Iris Syndrome (IFIS). In patients with moderate renal impairment, Silodosin dose should be reduced to 4 mg once daily.

**Overdose :** Silodosin was evaluated at doses of up to 48mg/day in healthy male subject. Dose limiting adverse event was postural hypotension. Overdose of silodosin may lead to hypotension.

**Storage :** Store at room temperature away from light and moisture. Keep all medications away from children.

**Packing : Silofast-4 :** Each box contains 2 x 10's capsules in blister pack.

**Silofast-8 :** Each box contains 2 x 10's capsules in blister pack.