

# Siloflo

Silodosin INN

**Composition:**

**Siloflo 4 Capsule:** Each capsule contains Silodosin INN 4 mg.

**Siloflo 8 Capsule:** 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 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].

**Contraindications:**

Patients with severe renal & hepatic impairment, concomitant administration with strong Cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ketoconazole, clarithromycin, itraconazole, ritonavir) and patients with a history of hypersensitivity to Silodosin.

**Side effects:**

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

**Warnings and Precautions:**

- Postural hypotension with or without symptoms (e.g. dizziness) may develop when beginning Silodosin treatment
- Silodosin 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)

**Use in special groups:**

**Pregnancy:** Silodosin is not indicated for use in women.

**Pediatric patients:** Silodosin is not indicated for use in pediatric patients.

**Renal impairment:** Silodosin should be reduced to 4 mg per day in patients with moderate renal impairment. Silodosin is contraindicated in patients with severe renal impairment.

**Hepatic impairment:** No dosing adjustment is required in patients with mild or moderate hepatic impairment. Silodosin is contraindicated in patients with severe hepatic impairment.

**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.

**Storage:**

- Store below 30<sup>o</sup> C, keep in dry place & protect from light
- Keep out of the reach of children

**Packing:**

**Siloflo 4 Capsule:** Each box contains 20 capsules in alu-alu blister pack.

**Siloflo 8 Capsule:** Each box contains 20 capsules in alu-alu blister pack.

Manufactured by:  
 **ARISTOPHARMA LTD.**  
Shampur-Kadamtai I/A, Dhaka-Bangladesh

200025/10/01