

## SILOXIO 4/ SILOXIO 8

### For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for SILOXIO 4/ SILOXIO 8 [Silodosin Capsules 4 mg and 8 mg]  
[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

#### PHARMACOLOGICAL PROPERTIES:

**MECHANISM OF ACTION:** 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:** For the treatment of signs and symptoms of benign prostatic hyperplasia (BPH) in adults only.

**DOSAGE AND ADMINISTRATION:** The recommended dosage is 1 capsule once daily or as directed by the Physician. For oral administration only.

**CONTRAINDICATION:** Silodosin is contraindicated for use in severe renal impairment (CCr <30 mL/min) and concomitant administration with strong CYP3A4 inhibitors (e.g. ketoconazole, clarithromycin, itraconazole, ritonavir).

**WARNINGS & PRECAUTIONS:** Postural hypotension, with or without symptoms (e.g., dizziness) may develop when beginning silodosin treatment. As with other alpha-blockers, there is potential for syncope. Patients should be cautioned about driving, operating machinery, or performing hazardous tasks when initiating therapy. The dose of silodosin should be reduced to 4 mg in patients with moderate renal impairment. Exercise caution and monitor such patients for adverse events. Silodosin is contraindicated in patients with severe renal impairment. Concomitant use of ketoconazole or other strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin, ritonavir) is therefore contraindicated. Caution is also advised when alpha-adrenergic blocking agents including silodosin are co-administered with PDE5 inhibitors. Alpha-adrenergic blockers and PDE5 inhibitors are both vasodilators that can lower blood pressure. Concomitant use of these two drug classes can potentially cause symptomatic hypotension. Therefore, patients thought to have BPH should be examined prior to starting therapy with silodosin to rule out the presence of carcinoma of the prostate.

**DRUG INTERACTIONS:** Use of strong CYP3A4 inhibitors such as itraconazole or ritonavir may cause plasma concentrations of silodosin to increase. Concomitant administration of strong CYP3A4 inhibitors and silodosin is contraindicated. Exercise caution and monitor patients for adverse events when co-administering silodosin with moderate CYP3A4 inhibitors. Inhibition of P-gp may lead to increased silodosin concentration. silodosin is therefore not recommended in patients taking strong P-gp inhibitors such as cyclosporine. Exercise caution during concomitant use with antihypertensives and monitor patients for possible adverse events. Patients should be instructed to take silodosin with a meal to reduce risk of adverse events.

**ADVERSE REACTIONS:** Toxic skin eruption, purpura, skin rash, pruritus, urticaria, jaundice, impaired hepatic function associated with increased transaminase values, allergic-type reactions, not limited to skin reactions including swollen tongue and pharyngeal edema resulting in serious outcomes, Retrograde ejaculation, Dizziness, Diarrhoea, Orthostatic hypotension, Headache, Nasopharyngitis, Nasal congestion.

#### MARKETED BY:



Torrent Pharmaceuticals Limited.

IN/ SILOXIO 4 mg/8mg/SEP-2025/01/ABPI

(Additional information is available on request)