

SILOXIO D

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

Abbreviated Prescribing information for SILOXIO D [Silodosin and Dutasteride Capsules 8 mg]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Silodosin*-Silodosin is a selective antagonist of post-synaptic alpha1-adrenoreceptors, which are located in the human prostate, bladder base, bladder neck, prostatic and prostatic urethra. Blockade of these alpha1-adrenoreceptors can cause smooth muscle in these tissues to relax, resulting in an improvement in urine flow and a reduction in benign prostatic hyperplasia (BPH) symptoms. An in vitro study examining the binding affinity of silodosin to the three subtypes of the alpha1-adrenoreceptors (alpha1A, alpha1B, and alpha1D) was conducted. The results of the study demonstrated that silodosin binds with high affinity to the alpha1A subtype. *Dutasteride*-Dutasteride inhibits the conversion of testosterone to 5 alpha-dihydrotestosterone (DHT) by a competitive and specific inhibition of both the type I and type II isoforms of steroid 5 alpha-reductase (5AR). Testosterone is converted to DHT by the enzyme 5 alpha-reductase, which exists as 2 isoforms, type I and type II. The type II isoenzyme is primarily active in the reproductive tissues, while the type I isoenzyme is also responsible for testosterone conversion in the skin and liver. DHT is the androgen primarily responsible for the initial development and subsequent enlargement of the prostate gland.

INDICATION It is indicated for the treatment of signs and symptoms of Benign Prostatic Hyperplasia (BPH) in men with an enlarged prostate.

DOSAGE AND ADMINISTRATION: The recommended dosage is 1 capsule once daily or as directed by the Physician. For oral administration only. Silodosin/Dutasteride capsules should be swallowed whole and must not be opened, crushed or chewed. The capsules may be taken with or without food.

CONTRAINDICATION: Silodosin/Dutasteride is contraindicated in patients with hypersensitivity to silodosin, dutasteride, other 5-alpha reductase inhibitors, or any other component of the Silodosin is contraindicated for use in the following: a) severe renal impairment (CCr<30mL/min). b) Concomitant administration with strong CYP3A4 inhibitors (e.g. ketoconazole, clarithromycin, itraconazole, ritonavir). Dutasteride is contraindicated for use in the following: a) women and children and adolescents. b) patients with severe hepatic impairment.

WARNINGS & PRECAUTIONS: *Silodosin*- 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. *Dutasteride*- Combination therapy should be prescribed after careful benefit risk assessment due to the potential increased risk of adverse events (including cardiac failure)

DRUG INTERACTIONS: There have been no drug interaction studies for Silodosin/Dutasteride. The following statements reflect the information available on the individual components.

ADVERSE REACTIONS: Tremor, nervousness, increased heart rate, palpitations, dizziness, headache, muscle cramps, transient rise in serum aminotransferase values, hypersensitivity reactions, skin rashes, nausea, vomiting (in large doses), drowsiness, sweating, shortness of breath, chest discomfort, weakness, anxiety, dry mouth, hypersensitivity, rare elevations in liver enzymes or hypersensitivity vasculitis.

MARKETED BY



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