

Sildodime D Capsule

Product Information: Silodosin (8mg) + Dutasteride (0.5mg) Capsule

Composition:

Each capsule contains:

- Silodosin: 8 mg
 - Dutasteride: 0.5 mg
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Pharmacological Class:

- Silodosin: Alpha-1 adrenergic blocker.
 - Dutasteride: 5-alpha-reductase inhibitor.
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Indications:

Silodosin (8mg) + Dutasteride (0.5mg) Capsule is indicated for the treatment of:

- **Benign Prostatic Hyperplasia (BPH):** This combination medication is used to treat symptoms of benign prostatic hyperplasia (BPH) in men, which include difficulty urinating, increased frequency of urination, and urinary retention. It helps relieve symptoms such as urinary urgency, weak urine stream, and frequent nighttime urination.

This combination therapy addresses both the smooth muscle component (via Silodosin) and the hormonal component (via Dutasteride) of BPH.

Mechanism of Action:

- **Silodosin:** Silodosin works by selectively blocking alpha-1A adrenergic receptors located in the smooth muscle of the prostate and bladder neck. This action relaxes the smooth muscle, which reduces the pressure on the urethra and facilitates urine flow, thus improving urinary symptoms of BPH.
 - **Dutasteride:** Dutasteride inhibits the enzyme 5-alpha-reductase, which converts testosterone to dihydrotestosterone (DHT). DHT is a potent androgen that is primarily responsible for prostate growth. By reducing DHT levels, Dutasteride helps shrink the prostate gland, reducing its size and alleviating symptoms of BPH.
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Dosage and Administration:

- **Usual Dose:** Take one capsule (containing 8 mg of Silodosin and 0.5 mg of Dutasteride) once daily with food.
 - **Administration:** The capsule should be swallowed whole with a glass of water. Do not chew, crush, or open the capsule.
 - **Duration of Treatment:** Treatment duration varies, but the combination therapy typically takes 3-6 months for optimal effects in reducing prostate size and improving urinary symptoms.
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Contraindications:

- **Hypersensitivity to Silodosin, Dutasteride, or any of the capsule's excipients.**
- **Severe hepatic impairment:** Use of this combination medication is contraindicated in patients with severe liver disease.
- **Pregnancy:** Dutasteride is contraindicated in women who are or may become pregnant because it can cause birth defects. Pregnant women should not handle broken or crushed capsules.
- **Women and Children:** Not indicated for use in women or children.
- **Severe urinary tract infection or bladder obstruction:** Caution is required.

Warnings and Precautions:

- **Sexual Dysfunction:** Dutasteride has been associated with sexual side effects, including decreased libido, erectile dysfunction, and ejaculatory disorders. These side effects may persist even after stopping treatment.
- **Orthostatic Hypotension:** Silodosin can cause a sudden drop in blood pressure when standing up, leading to dizziness or fainting (orthostatic hypotension), particularly when starting treatment. Use caution when moving from a sitting or lying position to a standing position.
- **Liver Function:** Silodosin and Dutasteride should be used with caution in patients with mild to moderate hepatic impairment. Regular liver function tests may be required.
- **Prostate Cancer:** Dutasteride can lower prostate-specific antigen (PSA) levels, which are used to screen for prostate cancer. Therefore, PSA testing should be performed regularly, and a baseline PSA measurement is recommended before

starting treatment. Any changes in PSA levels should be interpreted with caution.

- **Breast Changes:** Male patients taking Dutasteride may experience breast tenderness or enlargement. Any breast changes should be evaluated by a healthcare provider.
- **Allergic Reactions:** Allergic reactions such as rash, itching, or swelling of the face, lips, or tongue may occur. Seek immediate medical attention if any of these symptoms arise.

Adverse Effects:

- **Common side effects:**
 - **Silodosin:** Dizziness, retrograde ejaculation (in which semen enters the bladder instead of being expelled), fatigue, headache, and nasal congestion.
 - **Dutasteride:** Decreased libido, erectile dysfunction, ejaculation disorders, and breast tenderness or enlargement.
- **Serious side effects:**
 - **Severe allergic reactions** (anaphylaxis, swelling of the face or throat).
 - **Breast cancer:** Although rare, there have been reports of male breast cancer in patients on Dutasteride therapy.
 - **Severe hypotension:** Especially in patients who are elderly or have low blood pressure.
 - **Hepatic dysfunction:** Jaundice, dark urine, and abdominal pain.

If any serious side effects occur, contact a healthcare provider immediately.

Drug Interactions:

- **Alpha-blockers:** Co-administration with other alpha-blockers may increase the risk of low blood pressure or orthostatic hypotension.
 - **CYP3A4 Inhibitors** (e.g., ketoconazole, ritonavir): Silodosin is metabolized by the CYP3A4 enzyme. Concomitant use with strong CYP3A4 inhibitors can increase the levels of Silodosin, potentially increasing the risk of side effects.
 - **CYP3A4 Inducers** (e.g., rifampin): May decrease the effectiveness of Silodosin by reducing its levels in the body.
 - **Dutasteride:** Caution should be exercised when using Dutasteride with other drugs that affect the liver enzyme systems, such as those that are strong inhibitors or inducers of CYP3A4.
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Use in Special Populations:

- **Pregnancy and Lactation:** Dutasteride is contraindicated in women who are pregnant or may become pregnant, as it may cause birth defects. The medication is not recommended during breastfeeding.
 - **Elderly:** Elderly patients may be more sensitive to the effects of Silodosin, particularly in relation to blood pressure changes and dizziness. Close monitoring is recommended.
 - **Renal and Hepatic Impairment:** Use with caution in patients with renal or hepatic impairment. Adjustments to the dosage may be needed based on the severity of the impairment.
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Storage:

- Store at room temperature (15–30°C).

- Keep the capsules in the original container to protect from moisture and light.
 - Keep out of reach of children.
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Packaging:

- Available in blister packs or bottles containing 30 capsules.
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Patient Instructions:

1. **Dosage:** Take the capsule once daily as prescribed by your healthcare provider. It is best to take the medication with food to improve absorption.
 2. **Missed Dose:** If a dose is missed, take it as soon as you remember, unless it is almost time for the next dose. Do not double the dose to make up for a missed one.
 3. **Monitoring:** Regular visits to your doctor are important to monitor for side effects and assess the effectiveness of treatment.
 4. **Side Effects:** Inform your healthcare provider if you experience any new or unusual symptoms, especially sexual dysfunction, dizziness, or any signs of allergic reactions.
 5. **Handling:** Avoid handling broken or crushed capsules, particularly if pregnant, as Dutasteride can be absorbed through the skin and may harm a developing fetus.
 6. **Avoiding Pregnancy:** Men using Dutasteride should use barrier methods (e.g., condoms) during sexual intercourse with women who are pregnant or may become pregnant to prevent exposure to the medication.
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Silodosin (8mg) + Dutasteride (0.5mg) Capsule is an effective treatment for managing symptoms of BPH by addressing both the mechanical obstruction caused by prostate enlargement and the hormonal factors contributing to prostate growth. It offers a combination of symptom relief and long-term benefit in prostate health. Always use this medication under the supervision of a healthcare provider for optimal results.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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