

Timshell B Eye Drop

Product Information: Timolol (5mg) + Brimonidine (2mg) Eye Drops

Composition

- **Timolol: 5 mg**
 - **Brimonidine: 2 mg**
 - **Excipients: Sterile aqueous base, as required.**
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Pharmacological Class

- **Class: Antiglaucoma combination product.**
 - **Mechanism of Action:**
 - **Timolol is a non-selective beta-adrenergic blocker that reduces intraocular pressure (IOP) by decreasing the production of aqueous humor (the fluid inside the eye). This helps reduce IOP, which is beneficial in the treatment of conditions such as glaucoma and ocular hypertension.**
 - **Brimonidine is an alpha-2 adrenergic agonist that works by reducing aqueous humor production and increasing uveoscleral outflow (the drainage of fluid from the eye). Together with Timolol, it helps further lower IOP in patients with glaucoma or ocular hypertension.**
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Indications

The Timolol (5mg) + Brimonidine (2mg) Eye Drops are indicated for the following conditions:

- 1. Glaucoma:**
 - **Open-Angle Glaucoma: Used to reduce elevated intraocular pressure in adults with open-angle glaucoma.**
 - 2. Ocular Hypertension:**
 - **For the reduction of intraocular pressure in patients with ocular hypertension.**
 - 3. Adjunctive Therapy:**
 - **Typically used when monotherapy with a single agent is insufficient to adequately control intraocular pressure.**
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Dosage and Administration

- **Adults:**
 - **The recommended dose is 1 drop in the affected eye(s), twice daily (morning and evening), or as directed by a healthcare provider.**
 - **If using other eye medications, allow at least 5 minutes between applying different drops to avoid dilution or inactivation of the medications.**
- **Pediatric Use:**
 - **The safety and efficacy of Timolol + Brimonidine eye drops in children under the**

age of 2 have not been well established. For pediatric patients over 2 years of age, dosing should be determined by a healthcare provider.

- **Missed Dose:**
 - If a dose is missed, instill the drop as soon as you remember, unless it is close to the time for your next dose. Do not apply two doses at once to make up for a missed dose.

Contraindications

- **Hypersensitivity:** Contraindicated in patients with known hypersensitivity to Timolol, Brimonidine, or any other component of the formulation.
- **Asthma or COPD:** Contraindicated in patients with asthma, chronic obstructive pulmonary disease, or other serious respiratory conditions.
- **Bradycardia or Heart Block:** Contraindicated in patients with severe bradycardia (slow heart rate), second- or third-degree heart block, or uncontrolled heart failure.
- **Severe Depression or Monoamine Oxidase Inhibitor (MAOI) Use:** Contraindicated in patients with depression or using MAOIs due to the risk of serious drug interactions.

Warnings and Precautions

1. **Cardiovascular Effects:**
 - Use with caution in patients with a history of heart disease, bradycardia, cardiac failure, or hypotension. Both Timolol and Brimonidine can cause

systemic effects, including bradycardia and hypotension.

2. **Respiratory Concerns:**

- Timolol can exacerbate bronchospasm in patients with asthma or chronic obstructive pulmonary disease (COPD).

3. **CNS Effects:**

- Brimonidine can cross the blood-brain barrier and may cause sedation, fatigue, and drowsiness. Caution should be exercised when performing tasks requiring mental alertness.

4. **Masking of Hypoglycemia:**

- Timolol may mask the symptoms of hypoglycemia (low blood sugar) in diabetic patients, so it should be used with caution in such patients.

5. **Diabetes and Hyperthyroidism:**

- Timolol should be used cautiously in patients with diabetes or hyperthyroidism, as it may mask symptoms of these conditions.

6. **Pregnancy and Lactation:**

- **Pregnancy:** Timolol and Brimonidine should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.
- **Breastfeeding:** Both Timolol and Brimonidine are excreted in human milk. The use of this product in breastfeeding mothers should be avoided unless deemed necessary by a healthcare provider.

Adverse Effects

- **Common:**
 - **Burning, stinging, or discomfort in the eye immediately after instillation.**
 - **Redness of the eye, blurred vision, or mild tearing.**
 - **Fatigue or drowsiness (more common with Brimonidine).**
 - **Less Common:**
 - **Headache, dry eyes, or increased sensitivity to light.**
 - **Bradycardia, dizziness, or hypotension (with systemic absorption).**
 - **Serious:**
 - **Severe allergic reactions such as rash, itching, swelling, or difficulty breathing.**
 - **Bradycardia, heart block, or signs of heart failure.**
 - **Severe drowsiness, mental confusion, or dizziness.**
 - **If any of these occur, seek immediate medical attention.**
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Drug Interactions

- **Other Beta-blockers:** Concurrent use with other beta-blockers (oral or topical) may increase the risk of additive systemic beta-blockade effects, such as bradycardia or hypotension.
- **Calcium Channel Blockers:** Use with caution as they may have an additive effect on lowering heart rate and blood pressure.
- **Centrally Acting Antihypertensives:** Such as clonidine. These drugs may interact with Brimonidine and increase the risk of low blood pressure and bradycardia.

- **Tricyclic Antidepressants:** May enhance the sedative effects of Brimonidine.
 - **Digoxin:** Timolol may increase the serum concentration of digoxin and the risk of bradycardia.
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Storage Instructions

- **Storage:** Store at room temperature (15°C to 25°C), away from heat and direct light.
 - **Do not freeze.**
 - **Keep the bottle tightly closed when not in use.**
 - **Keep out of reach of children.**
 - **Use within 28 days after opening the bottle.**
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Clinical Benefits

- **Dual Mechanism for IOP Reduction:** The combination of Timolol and Brimonidine provides complementary mechanisms to lower intraocular pressure, making it more effective than monotherapy in many patients.
 - **Convenient Dosing:** The combination allows for easier management of IOP with fewer drops required per day, improving patient compliance.
 - **Well-Established Efficacy:** Both Timolol and Brimonidine are well-established treatments for glaucoma and ocular hypertension with proven long-term effectiveness.
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Packaging

- Available in 5 mL or 10 mL sterile dropper bottles.
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Timolol (5mg) + Brimonidine (2mg) Eye Drops offer an effective combination therapy for the management of elevated intraocular pressure in patients with glaucoma or ocular hypertension. The dual action of these two medications provides comprehensive control of IOP, helping to protect against optic nerve damage and preserve vision.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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