Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% and 10%

**Non-Refrigerated**

Now Available and Approved by the FDA

The ONLY Non-Refrigerated Product on the Market

*Store at 20° to 25°C (68° to 77°F)*

Convenient 2 mL 2.5% Size Offered

*2 mL 2.5% Size Exclusive to Akorn*

15 mL 2.5% and 5 mL 10% Also Available

24-Month Shelf Life

Phenylephrine Hydrochloride Ophthalmic Solution is an alpha-1 adrenergic receptor agonist for topical ophthalmic use, indicated to dilate the pupil. The product is used in ophthalmology mainly for its mydriatic effect.

**SELECT IMPORTANT SAFETY INFORMATION**

Phenylephrine hydrochloride ophthalmic solution 10% is contraindicated in patients with hypertension or thyrotoxicosis. It is also contraindicated for pediatric patients less than 1 year of age due to increased risk of systemic toxicity.

Ocular adverse reactions include eye pain and stinging on instillation, temporary blurred vision, and photophobia.

Cardiovascular adverse reactions include increase in blood pressure, syncope, myocardial infarction, tachycardia, arrhythmia and subarachnoid hemorrhage.

To Order Visit AkornDirect.com, Call 800-932-5676, or Contact Your Wholesaler/Distributor

NOT FOR PRESCRIBING PURPOSES. PLEASE REFER TO INCLUDED PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.
Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% and 10%

<table>
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<tr>
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<th>DESCRIPTION</th>
<th>SIZE</th>
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<td>2.5% Sterile Ophthalmic Solution</td>
<td>2 mL</td>
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<tr>
<td>17478-201-15</td>
<td>2.5% Sterile Ophthalmic Solution</td>
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<td>17478-206-05</td>
<td>10% Sterile Ophthalmic Solution</td>
<td>5 mL</td>
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**NDC CARDINAL AMERISOURCEBERGEN MCKESSON MORRIS DICKSON**

**EACH mL CONTAINS**

**ACTIVE:**
- Phenylephrine Hydrochloride 25 mg (2.5%); Phenylephrine Hydrochloride 100 mg (10%);

**INACTIVES:**
- Benzalkonium Chloride 0.1 mg (0.01%);
- Sodium Phosphate Monobasic, Sodium Phosphate Dibasic, Water for Injection. Phosphoric Acid and/or Sodium Hydroxide may be added to adjust pH (4.0 to 7.5). The solution has a tonicity of 340 mOsm/kg.

**STORAGE:**
- Store at 20° to 25°C (68° to 77°F).

**CONTRAINDICATIONS**
- The 10% strength is contraindicated in:
  - Patients with hypertension, or thyrotoxicosis (4.1)
  - Pediatric patients less than 1 year of age due to increased risk of systemic toxicity (4.2)

**WARNINGS AND PRECAUTIONS**
- Not for injection: Topical ophthalmic use only (5.1)
- Serious cardiovascular reactions with 10% strength: Reactions have included ventricular arrhythmias and some have been fatal. Monitor blood pressure in patients with cardiovascular disease (5.2).
- Significant elevations in blood pressure: Caution in pediatric patients less than 5 years of age, and in patients with cardiovascular disease or hyperthyroidism. In patients at high risk, monitor blood pressure post treatment (5.3).
- Rebound miosis: Reported one day after instillation (5.4)

**ADVERSE REACTIONS**
- Ocular adverse reactions include eye pain and stinging on instillation, temporary blurred vision, and photophobia (6.1)
- Cardiovascular adverse reactions include increase in blood pressure, syncope, myocardial infarction, tachycardia, arrhythmia and subarachnoid hemorrhage (6.2)

To report SUSPECTED ADVERSE REACTIONS, contact Akorn, Inc. at 1-800-932-5676 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

**DRUG INTERACTIONS**
- Atropine-like drugs: May exaggerate the adrenergic pressor response (7.1)
- Potent inhalation anesthetic agents: May potentiate cardiovascular depressant effects (7.1)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 01/2015

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Phenylephrine Hydrochloride Ophthalmic Solution is an alpha-1 adrenergic receptor agonist indicated to dilate the pupil.

**INDICATIONS AND USAGE**

Phenylephrine Hydrochloride Ophthalmic Solution is indicated to dilate the pupil.

**DOSE AND ADMINISTRATION**

- Apply one drop of Phenylephrine Hydrochloride Ophthalmic Solution (2.5% or 10% strength) to conjunctival fornix at 3 to 5 minute intervals up to a maximum of 3 drops per eye.
- To obtain a greater degree of mydriasis, use 10% strength
- Instill one drop of 2.5% strength to conjunctival fornix at 3 to 5 minute intervals up to a maximum of 3 drops per eye.

**CONTRAINDICATIONS**

The 10% strength is contraindicated in:

- Patients with hypertension, or thyrotoxicosis
- Pediatric patients less than 1 year of age due to increased risk of systemic toxicity

**DOSAGE FORMS AND STRENGTHS**

- Ophthalmic solution (sterile): (3) 25 mg of phenylephrine hydrochloride in one mL of solution (2.5%)
- Ophthalmic solution containing phenylephrine hydrochloride 10%: each mL contains 100 mg of phenylephrine hydrochloride.
- Ophthalmic solution 2.5% should be instilled at 3 to 5 minute intervals up to a maximum of 3 drops per eye.

**WARNINGS AND PRECAUTIONS**

- Not for injection: Topical ophthalmic use only (5.1)
- Serious cardiovascular reactions with 10% strength: Reactions have included ventricular arrhythmias and some have been fatal. Monitor blood pressure in patients with cardiovascular disease (5.2).
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Revised: 01/2015
phenylephrine hydrochloride ophthalmic solution. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.  

6.1 Ocular Adverse Reactions  
Eye pain and stinging on instillation, temporary blurred vision and photophobia, and conjunctival sensitization may occur.  

6.2 Systemic Adverse Reactions  
A marked increase in blood pressure has been reported particularly, but not limited to low weight premature neonates, infants and hypertensive patients. Cardiovascular effects which have been seen primarily in hypertensive patients following topical ocular use of phenylephrine hydrochloride ophthalmic solution 10% include marked increase in blood pressure, syncope, myocardial infarction, tachycardia, arrhythmia and subarachnoid hemorrhage [See Warnings and Precautions (5.2 and 5.3)].  

7 DRUG INTERACTIONS  

7.1 Agents That May Exaggerate Pressor Responses  
Concomitant use of phenylephrine and atropine may enhance the pressor effects and induce tachycardia in some patients. Phenylephrine may potentiate the cardiovascular depressant effects of some inhalation anesthetic agents.  

7.2 Ocular Interactions  
Phenylephrine has no known ocular interactions. The anticholinergic effects of phenylephrine may potentiate the anticholinergic effects of other ocular miotics which are used as add-on therapy.  

7.3 Antihypertensive Agents  
Phenylephrine is a direct alpha-adrenergic agonist. The antihypertensive agents such as beta-blockers, calcium channel blockers and ACE inhibitors may increase the effects of topical phenylephrine.  

7.4 Calcium Channel Blockers  
Phenylephrine may potentiate the effects of calcium channel blockers such as amlodipine.  

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8 USE IN SPECIFIC POPULATIONS  

8.1 Pregnancy  
Animal reproduction studies have not been conducted with topical phenylephrine. It is also not known whether phenylephrine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Phenylephrine hydrochloride should be given to a pregnant woman only if clearly needed.  

8.3 Nursing Mothers  
It is not known whether this drug is excreted in human breast milk. Because many drugs are excreted in human milk, caution should be exercised when phenylephrine hydrochloride ophthalmic solution 2.5% and 10% is administered to a nursing woman.  

8.4 Pediatric Use  
Phenylephrine hydrochloride ophthalmic solution 10% is contraindicated in pediatric patients less than 1 year of age [See Contraindications (4.2)].  

8.5 Geriatric Use  
No overall differences in safety and effectiveness have been observed between elderly and younger adult patients.  

10 OVERDOSAGE  
Overdose of phenylephrine may cause a rapid rise in blood pressure. It may also cause headache, anxiety, nausea, and vomiting, and ventricular arrhythmias. Prompt injection of a rapidly acting alpha-adrenergic blocking agent such as phentolamine has been recommended.  

11 DESCRIPTION  
Phenylephrine Hydrochloride Ophthalmic Solution, USP is a sterile, clear, colorless, topical α-adrenergic agonist for ophthalmic use. The active ingredient is represented by the chemical structure

![Chemical Structure](image)

Chemical Name: (R)-3-hydroxy-α-[(methylamino)methyl]benzenemethanol hydrochloride.

Molecular Formula: C_{10}H_{15}NO.HCl

Molecular Weight: 203.67 g/mol

Each mL of Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% contains: ACTIVE: Phenylephrine Hydrochloride 25 mg (2.5%); INACTIVES: Sodium Phosphate Monobasic, Sodium Phosphate Dibasic, Water for Injection. Phosphoric Acid and/or Sodium Hydroxide may be added to adjust pH (4.0 to 7.5). The solution has a tonicity of 985 mOsm/kg; PRESERVATIVE: Benzalkonium Chloride 0.1 mg (0.01%).