Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% and 10%

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% and 10% safely and effectively. Refer to package insert on www.paragonbiotech.com for full prescribing information.

Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% and 10%
Initial U.S. Approval: 1939

INDICATIONS & USAGE
Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% and 10% is an alpha-1 adrenergic receptor agonist indicated to dilate the pupil [1].

DOSAGE & ADMINISTRATION
- For patients 1 year of age or older, apply one drop of Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% or 10% at 3 to 5 minute intervals up to a maximum of 3 drops per eye [2, 7].
- In pediatric patients less than 1 year of age, one drop of Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% should be instilled at 3 to 5 minute intervals up to a maximum of 3 drops per eye [2, 2].

DOSAGE FORMS & STRENGTH
- 2.5% and 10% sterile ophthalmic solutions [3].

CONTRAINDICATIONS
- Phenylephrine Hydrochloride Ophthalmic Solution, USP 10% is contraindicated in patients with hypertension, or thyrotoxicosis. Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% should be used in these patients [4, 1].
- Phenylephrine Hydrochloride Ophthalmic Solution, USP 10% is contraindicated in pediatric patients less than 1 year of age due to the increased risk of systemic toxicity. Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% should be used in these patients [4, 2].

WARNINGS & PRECAUTIONS
- Not for injection. Topical ophthalmic use only [5, 1].
- Reports of serious cardiovascular reactions, some fatal, with phenylephrine hydrochloride 10% solution. Monitor blood pressure in patients with cardiovascular disease [5-2].
- Significant elevations in blood pressure have been reported. Caution in pediatric patients less than 5 years of age, and in patients with elevated blood pressure [5, 3].
- Rebound miosis has been reported one day after instillation [5, 4].

ADVERSE REACTIONS
- Ocular adverse reactions include eye pain and stinging upon 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 Paragon BioTeck, Inc. at 1-888-424-1192 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS
- May exaggerate the adrenergic pressor response in patients taking atropine-like drugs [7, 1].
- May potentiate the cardiovascular depressant effects of potent inhalation anesthetic agents [7, 7].

STORAGE
- Store in a refrigerator at 2° to 8°C (36° to 46°F).

Visit dilatingdrops.com for more information.

Phenylephrine Hydrochloride Ophthalmic Solution, USP 2.5% and 10% distributed by Bausch + Lomb Inc, Division of Valeant Pharmaceuticals North America LLC.

<table>
<thead>
<tr>
<th>Wholesaler</th>
<th>10%, 5ml</th>
<th>2.5%, 15ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardinal</td>
<td>4885661</td>
<td>4885646</td>
</tr>
<tr>
<td>Sigma</td>
<td>3025-1</td>
<td>3020-1</td>
</tr>
<tr>
<td>McKesson</td>
<td>2000701</td>
<td>2000693</td>
</tr>
<tr>
<td>ABC</td>
<td>229-190</td>
<td>229-187</td>
</tr>
<tr>
<td>ABC/SAP</td>
<td>10118211</td>
<td>10118210</td>
</tr>
<tr>
<td>Bellco</td>
<td>496288</td>
<td>496296</td>
</tr>
<tr>
<td>HD Smith</td>
<td>3616554</td>
<td>3616562</td>
</tr>
<tr>
<td>Kinray</td>
<td>924001</td>
<td>923979</td>
</tr>
<tr>
<td>Castillo</td>
<td>1000017374</td>
<td>1000017381</td>
</tr>
<tr>
<td>Eye Supply</td>
<td>218601</td>
<td>218602</td>
</tr>
<tr>
<td>Accutome</td>
<td>AX0315</td>
<td>AX0310</td>
</tr>
</tbody>
</table>

Paragon BioTeck, Inc. | 4640 SW Macadam Ave, Ste 80 Portland, OR 97239 | (888) 424-1192 | www.paragonbiotech.com

Copyright © 2016 Paragon BioTeck, Inc. All Rights Reserved.