PHENYLEPHRINE HYDROCHLORIDE- phenylephrine hydrochloride solution
Bryant Ranch Prepack

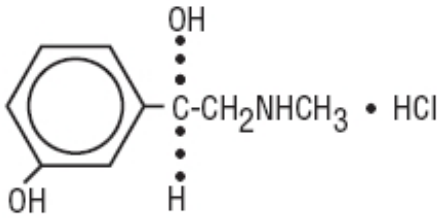
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Phenylephrine Hydrochloride Ophthalmic Solution USP, 2.5%
(Sterile)
Rx only

Warning: Physicians should completely familiarize themselves with the complete contents of this insert before prescribing Phenylephrine Hydrochloride.

DESCRIPTION:

Phenylephrine Hydrochloride Ophthalmic Solution, is a non-irritating, sterile solution containing sympathomimetic agent producing vasoconstrictor and mydriatic effects. Phenylephrine hydrochloride is a synthetic sympathomimetic and adrenergic compound structurally similar to epinephrine and ephedrine. A prompt, short acting mydriatic, it causes little or no cycloplegia or irritation. The active ingredient is represented by the chemical structural formula:



$C_9H_{13}NO_2$•HCl
Molecular Weight: 203.67

Chemical name:

Benzenemethanol, 3-hydroxy-α-[(methylamino)methyl]-, hydrochloride [R]-.

Each mL Contains:

ACTIVE: Phenylephrine Hydrochloride, 25 mg (2.5%); INACTIVES: Boric Acid, Sodium Borate, Sodium Bisulfite, Edetate Disodium and Purified Water. Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (4.0-7.5). PRESERVATIVE ADDED: Benzalkonium Chloride 0.01%.

CLINICAL PHARMACOLOGY:

Phenylephrine Hydrochloride Ophthalmic Solution possesses predominantly α-adrenergic effects. In the eye, phenylephrine acts locally as a potent vasoconstrictor and mydriatic, by constricting ophthalmic blood vessels and the radial muscle of the iris. The ophthalmologic usefulness of Phenylephrine Hydrochloride Ophthalmic Solution is due to its rapid effect and moderately prolonged action, as well as to the fact that it produces no compensatory vasodilation.

Although rare, systemic absorption of sufficient quantities of phenylephrine may lead to systemic α-adrenergic effects, such as rise in blood pressure which may be accompanied by a reflex atropine-sensitive bradycardia.

INDICATIONS AND USAGE:

As an ophthalmic decongestant and vasoconstrictor and for pupil dilation in uveitis (posterior synechiae), wide angle glaucoma, prior to surgery, refraction, ophthalmoscopic examination and diagnostic procedures.

CONTRAINDICATIONS:

As with other mydriatics, phenylephrine hydrochloride ophthalmic solution is contraindicated in patients with narrow angle glaucoma. This preparation is contraindicated in persons sensitive to any of its components.

WARNINGS:

Contains Sodium Bisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

For topical ophthalmic use only. As with all other adrenergic drugs, when administered simultaneously, or up to 21 days other administration of monoamine oxidase (MAO) inhibitors, careful supervision and adjustment of dosages are required since exaggerated adrenergic effects may result. The pressor response of adrenergic agents may also be potentiated by tricyclic antidepressants.

There have been rare reports associating the use of phenylephrine hydrochloride 10 percent ophthalmic solutions with the development of serious cardiovascular reactions, including ventricular arrhythmias and myocardial infractions. These episodes, some ending fatally, have usually occurred in elderly patients with preexisting cardiovascular diseases.

PRECAUTIONS:

Exceeding recommended dosages or applying phenylephrine hydrochloride ophthalmic solutions to the instrumented, traumatized, diseased or postsurgical eye or adnexa, or to patients with suppressed lacrimation, as during anesthesia, may result in the absorption of sufficient quantities of phenylephrine to produce a systemic vasopressor response.

A significant elevation in blood pressure is rare but has been reported following conjunctival instillation of recommended doses of phenylephrine hydrochloride 10 percent ophthalmic solutions. Caution, therefore, should be exercised in administering the 10 percent solutions to pediatric patients of low body weight, the elderly, and patients with insulin-dependent diabetes, hypertension, hyperthyroidism, generalized arteriosclerosis, or cardiovascular disease. The posttreatment blood pressure of these patients, and any patients who develop symptoms, should be carefully monitored.

Ordinarily, any mydriatic, including phenylephrine hydrochloride ophthalmic solution, is contraindicated in patients with glaucoma, since it may occasionally raise intraocular pressure. However, when temporary dilatation of the pupil may free adhesions or when vasoconstriction of intrinsic vessels may lower intraocular tension, these advantages may temporarily outweigh the danger from coincident dilatation of the pupil.

Rebound miosis has been reported in older persons one day after receiving phenylephrine hydrochloride ophthalmic solutions, and reinstallation of the drug produced a reduction in mydriasis. This may be of clinical importance in dilating the pupils of older subjects prior to retinal detachment or cataract surgery.

Due to strong action of the drug on the dilator muscle, older individuals may also develop transient pigment floaters in the aqueous humor 30 to 45 minutes following the administration of phenylephrine hydrochloride ophthalmic solutions. The appearance may be similar to anterior uveitis or to a

microscopic hyphema.

To prevent pain, a drop of suitable topical anesthetic may be applied before using the 2.5 percent ophthalmic solution.

Drug Interaction:

As with all other adrenergic drugs, when phenylephrine hydrochloride 2.5 percent ophthalmic solution is administered simultaneously with, or up to 21 days after, administration of monoamine oxidase (MAO) inhibitors, careful supervision and adjustment of dosages are required since exaggerated adrenerglc effects may occur. The pressor response of adrenergic agents may also be potentiated by tricyclic antidepressants, propranolol, reserpine, guanethidine, methyldopa, and atropine-like drugs.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

No long-term animal studies have been done to evaluate the potential of phenylephrine hydrochloride ophthalmic solutions in these areas

Pregnancy Category C:

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

Nursing Mothers:

It is not known whether this drug is excreted in milk; many are. Caution should be exercised when phenylephrine hydrochloride ophthalmic solution is administered to a nursing woman.

Pediatric Use:

Phenylephrine hydrochloride 10 percent ophthalmic solutions are contraindicated in infants. (See CONTRAINDICATIONS.) For use in older pediatric patients see DOSAGE AND ADMINISTRATION. Exceeding recommended dosages or applying phenylephrine hydrochloride ophthalmic solutions to the instrumented, traumatized, diseased or postsurgical eye or adnexa, or to patients with suppressed lacrimation, as during anesthesia, may result in the absorption of sufficient quantities of phenylephrine to produce a systemic vasopressor response.

The hypertensive effects of phenylephrine may be treated with an alpha-adrenergic blocking agent such as phentolamine mesylate, 5 mg to 10 mg intravenously, repeated as necessary.

DO NOT USE IF SOLUTION IS BROWN OR CONTAINS A PRECIPITATE. DO NOT TOUCH DROPPER TIP TO ANY SURFACE, SINCE THISMAY CONTAMINATE THE SOLUTION.

ADVERSE REACTIONS

Phenylephrine is a sympathomimetic drug related to epinephrine and ephedrine, and that even though it is rare, it may produce such reactions as tremor, pallor, perspiration, abnormal palpitation or collapse.

DOSAGE AND ADMINISTRATION

Vasoconstriction and Pupil Dilation:

Phenylephrine Hydrochloride Ophthalmic Solution USP, 2.5% is especially useful when rapid and power ful dilation of the pupil without cycloplegia and reduction of congestion in the capillary bed are desired. A drop of a suitable topical anesthetic may be applied, followed in a few minutes by 1 drop of Phenylephrine Hydrochloride Ophthalmic Solution USP, 2.5% on the upper limbus. The anesthetic

prevents stinging and consequent dilution of the solution by lacrimation. It may occasionally be necessary to repeat the instillation after one hour, again preceded by the use of the topical anesthetic. *Uveitis:* Posterior Synechiae: Phenylephrine Hydrochloride Ophthalmic Solution USP, 2.5% may be used in patients with uveitis when synechiae are present or may develop. The formation of synechiae may be prevented by the use of this solution and atropine or other cycloplegics to produce wide dilation of the pupil. For recently formed posterior synechiae one drop of Phenylephrine Hydrochloride Ophthalmic Solution USP, 2.5% may be applied to the upper surface of the cornea and be repeated as necessary, not to exceed three times. Treatment may be continued the following day, if necessary. Atropine sulfate and the application of hot compresses should also be used if indicated.

Glaucoma

Phenylephrine hydrochloride ophthalmic solution may be used with miotics in patients with wide angle glaucoma. It reduces the difficulties experienced by the patient because of the small field produced by miosis, and still it permits and often supports the effect of the miotic in lowering the intraocular pressure. Hence, there may be marked improvement in visual acuity after using phenylephrine hydrochloride in conjunction with miotic drugs.

Surgery

When a short-acting mydriatic is needed for wide dilatation of the pupil before intraocular surgery, 2.5 percent ophthalmic solution may be applied topically from 30 to 60 minutes before the operation.

Refraction

Prior to determination of refractive errors, phenylephrine hydrochloride 2.5 percent ophthalmic solution may be used effectively with homatropine hydrobromide, atropine sulfate, or a combination of homatropine and cocaine hydrochloride.

For *adults,* a drop of the preferred cycloplegic is placed in each eye, followed in five minutes by 1 drop of phenylephrine hydrochloride 2.5 percent ophthalmic solution and in ten minutes by another drop of the cycloplegic. In 50 to 60 minutes, the eyes are ready for refraction.

For older pediatric patients, a drop of atropine sulfate 1 percent is placed in each eye, followed in 10 to 15 minutes by 1 drop of phenylephrine hydrochloride 2.5 percent ophthalmic solution and in five to ten minutes by a second drop of atropine sulfate 1 percent. In one to two hours, the eyes are ready for refraction.

For a "one application method," phenylephrine hydrochloride 2.5 percent ophthalmic solution may be combined with a cycloplegic to elicit synergistic action. The additive effect varies depending on the patient. Therefore, when using a "one application method," it may be desirable to increase the concentration of the cycloplegic.

Ophthalmoscopic Examination

One drop phenylephrine hydrochloride 2.5 percent ophthalmic solution is placed in each eye. Sufficient mydriasis to permit examination is produced in 15 to 30 minutes. Dilatation lasts from one to three hours.

Diagnostic Procedures

Provocative Test for Angle Block in Patients with Glaucoma: The 2.5 percent ophthalmic solution may be used as a provocative test when latent increased intraocular pressure is suspected. Tension is measured before application of phenylephrine hydrochloride and again after dilatation. A 3 to 5 mm of mercury rise in pressure suggests the presence of angle block in patients with glaucoma; however, failure to obtain such a rise does not preclude the presence of glaucoma from other causes.

Shadow Test (Retinoscopy): When dilatation of the pupil without cycloplegic action is desired for the shadow test, the 2.5 percent ophthalmic solution may be used alone.

Blanching Test: One or 2 drops of the 2.5 percent ophthalmic solution should be applied to the injected

eye. After five minutes, examine for perilimbal blanching. If blanching occurs, the congestion is superficial and probably does not indicate iritis.

DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.

HOW SUPPLIED:

Phenylephrine Hydrochloride Ophthalmic Solution USP, 2.5%, is supplied in a plastic squeeze bottle with a controlled drop tip in the following sizes:

2 mL bottle - Prod. No. 05303

5 mL bottle - Prod. No. 05307

15 mL bottle - Prod. No. 05311

STORAGE:

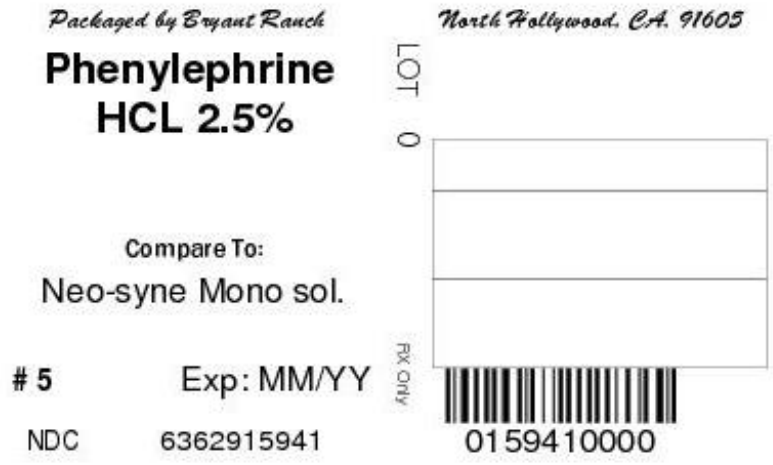
Store in a refrigerator at 2°-8°C (36°-46°F). KEEP TIGHTLY CLOSED.

KEEP OUT OF REACH OF CHILDREN.

Revised December 2007

Bausch & Lomb Incorporated
Tampa, FL 33637

Phenylephrine HCL 2.5%



PHENYLEPHRINE HYDROCHLORIDE

phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63629-1594(NDC:24208-740)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SODIUM BISULFITE (UNII: TZX5469Z6I)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63629-1594-1	5 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		09/30/1990	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-1594) , RELABEL(63629-1594)

Revised: 4/2013 Bryant Ranch Prepack