PRESCRIBING INFORMATION

MYDFRIN*

Phenylephrine Hydrochloride Ophthalmic Solution

Vasoconstrictor and Mydriatic for Use in Ophthalmology

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MYDFRIN*
Phenylephrine Hydrochloride Ophthalmic Solution
2.5% w/v
Vasoconstrictor and Mydriatic for Use in Ophthalmology

PHYSICIANS SHOULD COMPLETELY FAMILIARIZE THEMSELVES WITH THE COMPLETE CONTENTS OF THIS LEAFLET BEFORE PRESCRIBING PHENYLEPHRINE HYDROCHLORIDE.

DESCRIPTION: MYDFRIN* (phenylephrine hydrochloride ophthalmic solution) is a sterile ophthalmic solution containing:
Medicinal Ingredient: Phenylephrine HCl 2.5% w/v.
Non-medicinal Ingredients: Benzalkonium Chloride 0.01% w/v (preservative), Boric Acid, Sodium Bisulfite, Edetate Disodium, Sodium Hydroxide and/or Hydrochloric Acid (to adjust pH), Purified Water.

ACTION: Phenylephrine hydrochloride is used for local ocular disorders because of its vasoconstrictor and mydriatic action. The usefulness of phenylephrine hydrochloride in ophthalmology is due to its rapid effect, moderately prolonged action, and effectiveness even when administered repeatedly, as well as to the fact that it produces little rebound vasodilation. In addition, undesirable systemic side effects are uncommon. As an alpha receptor stimulator, MYDFRIN* produces pupillary dilatation and vasoconstriction.

INDICATIONS: MYDFRIN* is recommended as a vasoconstrictor, decongestant, and mydriatic in a variety of ophthalmic conditions and procedures. Some of its uses are for pupillary dilatation in uveitis (to prevent posterior synechia formation), for multiple ophthalmologic surgical procedures (including phacoemulsification, intracapsular and extracapsular cataract extraction, vitrectomy, etc.), and for refraction without cycloplegia (as an adjunct to increase pupillary dilatation). MYDFRIN* may also be used for fundoscopy, multiple ophthalmic diagnostic procedures and examination.

CONTRAINDICATIONS: MYDFRIN* is contraindicated in:

- Patients with hypersensitivity to phenylephrine hydrochloride or to any ingredient in the formulation or component of the container.
- Patients with anatomically narrow angles or narrow angle glaucoma.
- Newborns and infants with cardiovascular or cerebrovascular disease.
- Some elderly adults with severe arteriosclerotic cardiovascular or cerebrovascular disease.

MYDFRIN* may be contraindicated during intraocular operative procedures when the corneal epithelial barrier has been disturbed.

WARNINGS AND PRECAUTIONS: Ordinarily, any mydriatric, including phenylephrine hydrochloride, 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 the ciliary body vascular may lower intraocular tension, these advantages may temporarily outweigh the danger from coincident dilatation of the pupil.

MYDFRIN* should be used with caution in children, the elderly and in patients with sympathetic denervation (e.g. patients with insulin dependent diabetes, orthostatic hypotension, hypertension, hyperthyroidism).

Systemic absorption may be enhanced when applying MYDFRIN* to an instrumented, traumatized, diseased or postsurgical eye or adnexa, or to patients with suppressed lacrimation as during anesthesia.

Studies have not been performed to evaluate the effect of ocular administration of MYDFRIN* on fertility.

Nasolacrimal occlusion or gently closing the eyelid after administration is recommended. This may reduce the systemic absorption of medicinal products administered via the ocular route and may result in a decrease in systemic adverse reactions.

To prevent pain, a drop of suitable topical anesthetic may be applied before using MYDFRIN*.

MYDFRIN* contains the preservative benzalkonium chloride, which may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. Patients must be instructed to remove contact lenses prior to application of MYDFRIN* and wait at least 15 minutes before re-insertion.

Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient must wait until the vision clears before driving or using machinery.

Prolonged exposure to air or strong light may cause oxidation and discoloration. Do not use if solution is brown or contains a precipitate.

Drug Interactions: MYDFRIN* should be used with caution, if at all, in patients taking monoamine oxidase inhibitors (MAOIs), tricyclic antidepressants, certain antihypertensive agents (e.g. guanethidine, reserpine, and non-selective beta blockers, such as propranolol), or systemic atropine.

As with other adrenergic drugs, when MYDFRIN* is administered simultaneously with, or up to 21-days after, administration of MAOIs, 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 and certain antihypertensive agents.

Concomitant use of phenylephrine and systemic atropine may enhance the pressor effects and induce tachycardia in some patients, especially infants.

Phenylephrine may potentiate the cardiovascular depressant effects of potent inhalation anesthetic agents.

Pregnant Women: There are no or limited amount of data from the use of MYDFRIN* in pregnant women. However, there is data with the systemic use of phenylephrine that suggest risk. MYDFRIN* is not recommended during pregnancy.

Nursing Women: It is not known whether phenylephrine or its metabolites are excreted into human milk. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from MYDFRIN* therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Pediatrics: The use in preterm and newborn infants is not recommended unless clearly necessary. Full-term, but especially low birth weight and premature infants, may be an increased risk for systemic adverse reactions including transient increases in blood pressure. The infant should be monitored after instillation, and routines to adequately deal with emergency situations should be in place. The lowest possible dose should be used. Instillation of more than one drop per eye must be avoided.

The lowest dose necessary to produce the desired effect should always be used in children.

Parents should be warned not to get MYDFRIN* in their children's mouth or cheeks and to wash their hands and the child's hands or cheeks following administration.

Geriatrics: Rebound miosis has been reported in elderly persons one day after receiving phenylephrine HCl ophthalmic solutions, and reinstallation of the drug produced a reduction in mydriasis. This may be of clinical importance in dilatation of the pupils of elderly subjects prior to retinal detachment or cataract surgery. Due to a strong action of the drug on the dilator muscle, elderly individuals may also develop transient pigment floaters in the aqueous humor 40 to 45 minutes following the administration of phenylephrine hydrochloride ophthalmic solution. The appearance may be similar to anterior uveitis or to a microscopic hyphema.

ADVERSE REACTIONS:
Cardiac disorders: blood pressure increased, tachycardia;
Eye disorders: conjunctivitis, eye irritation, eye pain, ocular hyperemia;
Immune system disorders: hypersensitivity;
Nervous system disorders: dizziness;
Respiratory, thoracic and mediastinal disorders: pulmonary edema;
Skin and subcutaneous tissue disorders: dermatitis contact.

Systemic toxicity can result from topical application of sympathicomimetic drugs; headache, blood pressure elevation, extrasystoles, tachycardia, syncope and cerebrovascular accidents have been reported.

OVERDOSE: In case of accidental ingestion, phenylephrine may cause hypertension, headache, seizures, cerebral hemorrhage, palpitations, paresthesia or vomiting. Pulmonary edema or cardiac arrest may occur.

Phenylephrine has a rapid and short duration of action; treatment of toxicity is supportive. The use of beta blockers and calcium channel blockers for the treatment of acute hypertension secondary to vasoconstriction should be avoided.

DOSAGE AND ADMINISTRATION:

Vasoconstriction and Pupil Dilatation: MYDFRIN* is especially useful when rapid and powerful dilatation of the pupil 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 MYDFRIN* 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 Synechia:* MYDFRIN* may be used in patients with uveitis when synechiae are present or may develop. The formation of synechia may be prevented by the use of MYDFRIN* and atropine to produce wide dilatation of the pupil. For recently formed posterior synchiae, one drop of MYDFRIN* may be applied to the upper surface of the cornea and may be repeated in one hour as necessary. Treatment may be continued the following day, if necessary, employing topical atropine sulfate and applying hot compresses as indicated.

GLAUCOMA: MYDFRIN* may be used with miotics in patients with open 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 MYDFRIN* in conjunction with miotic drugs.

SURGERY: When a short-acting mydriatic is needed for wide dilatation of the pupil before intraocular surgery, MYDFRIN* may be applied topically from 30 to 60 minutes before the operation.

REFRACTION: Prior to determination of refractive errors, MYDFRIN* may be used effectively with homatropine hydrobromide, cyclopentolate hydrochloride, tropicamide and topical atropine sulfate.

For adults: One drop of the preferred cycloplegic is placed in each eye, followed in 5 minutes by one drop of MYDFRIN*.

Since adequate cycloplegia is achieved at different time intervals after the instillation of the necessary number of drops, different cycloplegics will require different waiting periods to achieve adequate cycloplegia.

For children: Topical atropine sulfate is the preferred cycloplegic for children. Usually atropine sulfate ointment is placed into the interior cul-de-sac twice daily for 3 days prior to refraction. For a "one application method," MYDFRIN* may be combined with the preferred rapid acting cycloplegic to produce adequate cycloplegia.

OPHTHALMOSCOPIC EXAMINATION: One drop of MYDFRIN* 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 Closure Glaucoma:* MYDFRIN* may be used as a provocative test when interval narrow angle closure glaucoma is suspected.

Intraocular tension and gonioscopy are performed prior to and after dilatation of the pupil with phenylephrine hydrochloride. A "significant" intraocular pressure (IOP) rise combined with gonioscopic evidence of angle closure indicates an anterior segment anatomy capable of angel closure. This pharmacological induced angle closure glaucoma may not simulate real life conditions and other causes for transient elevations of IOP should be excluded.
SHADOW TEST (RETINOSCOPY): When dilatation of the pupil without cycloplegic action is desired for the shadow test, MYDFRIN* may be used.
BLANCHING TEST: One or two drops of MYDFRIN* should be applied to the infected eye. After five minutes, examine for perilimbal blanching. If branching occurs, the congestion is superficial and probably does not indicate iridocyclitis.
STORAGE: Protect from light and excessive heat.
HOW SUPPLIED: MYDFRIN* is available in 5 mL plastic DROP-TAINER* dispenser.

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