

PRESCRIBING INFORMATION

ODAN-PHENYLEPHRINE

Phenylephrine Hydrochloride Ophthalmic Solution USP

2.5%

Mydriatic / Vasoconstrictor

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 **ODAN**
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DESCRIPTION

ODAN-PHENYLEPHRINE is a sterile ophthalmic solution containing a sympathomimetic agent which produces both vasoconstricting and mydriatic effects. Phenylephrine hydrochloride is a synthetic sympathomimetic compound structurally similar to epinephrine and ephedrine. A prompt, short acting mydriatic, it causes little or no cycloplegia or irritation.

ACTIONS

Phenylephrine hydrochloride is presumed to have a direct effect upon the alpha-adrenergic receptor stimulator producing pupil dilation and vasoconstriction.

INDICATIONS

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

CONTRAINDICATIONS

Narrow-angle glaucoma, hypertension, and in persons with a known hypersensitivity to any component.

WARNINGS

For topical ophthalmic use only. As with all other adrenergic drugs, when 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 adrenergic effects may result. The pressor response of adrenergic agents may also be potentiated by tricyclic antidepressants .

PRECAUTIONS

ODAN-PHENYLEPHRINE should be used with caution in patients with advanced arteriosclerotic conditions or severe hypertension. Phenylephrine may be used in patients with glaucoma when temporary dilation 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 dilation of the pupil.

Do not use if solution is discolored or contains a precipitate.

Do not touch dropper tip to any surface, since this may contaminate the solution.

ADVERSE EFFECTS

It is well to bear in mind that phenylephrine is, in fact, a sympathomimetic drug related to epinephrine and ephedrine, and that although the incidence is rare, it may produce such reactions as tremor, pallor, perspiration, palpitation or collapse.

DOSAGE AND ADMINISTRATION

Topically, 1 or 2 drops into the conjunctiva of each eye for refraction, in conjunction with the cycloplegic of choice, and ophthalmoscopic examination. ODAN-PHENYLEPHRINE may be applied topically from 30 to 60 minutes prior to surgery.

AVAILABILITY

Each mL of sterile ophthalmic solution contains 25 mg Phenylephrine Hydrochloride USP and the following non-medicinal ingredients: boric acid, dibasic and monobasic sodium phosphate, water, and pH adjusted with phosphoric acid and/or sodium hydroxide. Contains benzalkonium chloride 0.01% as preservative. Available in 15 mL plastic squeeze bottles with dropper tip.

STORAGE CONDITIONS

Keep container tightly closed. Store between 2°C and 30°C, protect from light.