

PRESCRIBING INFORMATION

ODAN-TROPICAMIDE

Tropicamide Ophthalmic Solution, USP

0.5% and 1%

ANTICHOLINERGIC

ODAN LABORATORIES LTD.
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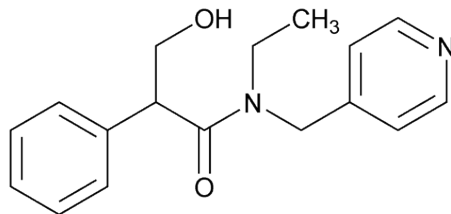

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ODAN-TROPICAMIDE **Tropicamide Ophthalmic Solution, USP** **0.5% and 1%**

DESCRIPTION

ODAN-TROPICAMIDE (Tropicamide Ophthalmic Solution, USP) is an anticholinergic prepared as a sterile topical ophthalmic solution in two strengths. The active ingredient is represented by the structural formula:



$C_{17}H_{20}N_2O_2$

MW=284.36

Common name: Tropicamide

Chemical name: Benzeneacetamide, N-ethyl- α -(hydroxymethyl)-N-(4-pyridinylmethyl)-.

Each mL contains:

Active Ingredient: Tropicamide 0.5% (5 mg) or 1% (10 mg).

Non Medicinal Ingredients: Edetate Disodium, Sodium Chloride, Hydrochloric Acid and/or Sodium Hydroxide (to adjust pH), Water for Injection. pH range 4.0 to 5.8.

Preservative: Benzalkonium Chloride 0.01%.

CLINICAL PHARMACOLOGY

This anticholinergic preparation blocks the responses of the sphincter muscle of the iris and the ciliary muscle to cholinergic stimulation, dilating the pupil (mydriasis). The stronger preparation (1%) also paralyzes accommodation. This preparation acts in 15-30 minutes and the duration of activity is approximately 3-8 hours. Complete recovery from mydriasis in some individuals may require 24 hours. The weaker strength (0.5%) may be useful in producing mydriasis with only slight cycloplegia. Heavily pigmented irides may require more doses than lightly pigmented irides.

INDICATIONS

For mydriasis and cycloplegia in diagnostic procedures. When a short acting mydriatic is

needed for some pre and post-operative states.

CONTRAINDICATIONS

This product is contraindicated in narrow-angle glaucoma, and in persons showing hypersensitivity to any component of this preparation.

WARNINGS

For topical use only — not for injection.

This preparation may cause CNS disturbances which may be dangerous in pediatric patients. The possibility of psychotic reactions and behavioral disturbances due to hypersensitivity to anticholinergic drugs should be considered.

Mydriatics may produce a transient elevation of intraocular pressure.

Remove contact lenses before using this product.

PRECAUTIONS

General: The lacrimal sac should be compressed by digital pressure for two to three minutes after instillation to avoid excessive systemic absorption.

Patient: Do not touch dropper tip to any surface, as this may contaminate the solution. Patient should be advised not to drive or engage in potentially hazardous activities while pupils are dilated. Patient may experience sensitivity to light and should protect eyes in bright illumination during dilation. Parents should be warned not to get this preparation in their child's mouth and to wash their own hands and the child's hands following administration.

Pediatric Use: Tropicamide may rarely cause CNS disturbances which may be dangerous in pediatric patients. Psychotic reactions, behavioral disturbances, and vasomotor or cardiorespiratory collapse in children have been reported with the use of anticholinergic drugs (See WARNINGS). Keep this and all medications out of the reach of children.

DRUG INTERACTIONS

Tropicamide may interfere with the antihypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors.

ADVERSE REACTIONS

Ocular: Transient stinging, blurred vision, photophobia and superficial punctate keratitis have been reported with the use of tropicamide. Increased intraocular pressure has been reported following the use of mydriatics.

Non-Ocular: Dryness of the mouth, tachycardia, headache, allergic reactions, nausea, vomiting, pallor, central nervous system disturbances and muscle rigidity have been reported with the use of tropicamide. Psychotic reactions, behavioral disturbances, and vasomotor or cardiorespiratory collapse in children have been reported with the use of anticholinergic drugs.

DOSAGE AND ADMINISTRATION

For refraction, instill one or two drops of 1% solution in the eye(s), repeated in five minutes. If patient is not seen within 20 to 30 minutes, an additional drop may be instilled to prolong mydriatic effect.

For examination of fundus, instill one or two drops of 0.5% solution 15 to 20 minutes prior to examination.

Individuals with heavily pigmented irides may require higher strength or more doses. Mydriasis will reverse spontaneously with time, typically in 4 to 8 hours. However, in some cases, complete recovery may take up to 24 hours.

AVAILABILITY

ODAN-TROPICAMIDE is available in two strengths, 0.5% and 1%; both are supplied as a sterile solution in 15 mL plastic dropper bottles.

STORAGE

Store between 15°C and 30°C. Do not refrigerate or store at high temperatures. Keep container tightly closed.