VASOCON- naphazoline hydrochloride solution
CIBA Vision

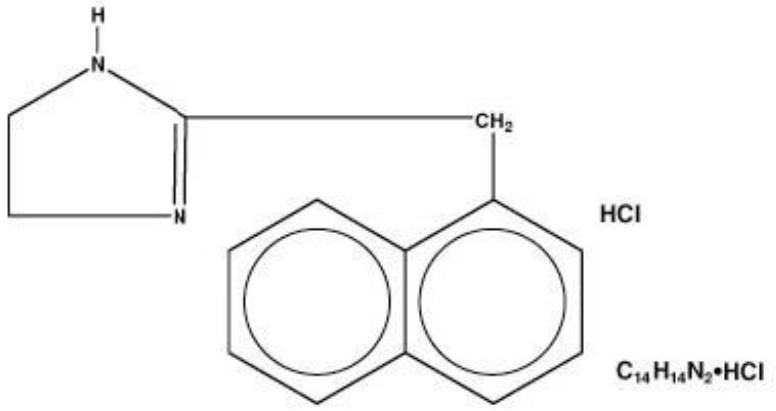
Vasocon

VASOCON REGULAR

NAPHAZOLINE HYDROCHLORIDE OPHTHALMIC SOLUTION USP, 0.1%

DESCRIPTION

Naphazoline HCl, an ocular vasoconstrictor, is an imidazoline derivative sympathomimetic amine. The active ingredient is represented by the structural formula:



Chemical Name:

2-(1-naphthylmethyl)-2-imidazoline monohydrochloride

VASOCON REGULAR ophthalmic solution is a sterile solution containing 1 mg/mL naphazoline hydrochloride in an isotonic solution containing polyethylene glycol 8000, sodium chloride, polyvinyl alcohol, edetate disodium and purified water; preserved with benzalkonium chloride. Hydrochloric acid and/or sodium hydroxide added to adjust pH. It has a pH of 5.5 to 7.0.

CLINICAL PHARMACOLOGY

Naphazoline constricts the vascular system of the conjunctiva. It is presumed that this effect is due to direct stimulation action of the drug upon the alpha adrenergic receptors in the arterioles of the conjunctiva resulting in decreased conjunctival congestion. Naphalozine belongs to the imidazoline class of sympathomimetics.

INDICATIONS AND USAGE

VASOCON REGULAR is indicated for use as a topical ocular vasoconstrictor.

CONTRAINDICATIONS

Contraindicated in the presence of an anatomically narrow angle or in narrow angle glaucoma or in persons who have shown hypersensitivity to any component of this preparation.

WARNINGS

Patients under therapy with MAO inhibitors may experience a severe hypertensive crisis if given a sympathomimetic drug. Use in children, especially infants, may result in CNS depression leading to coma and marked reduction in body temperature.

PRECAUTIONS

General

Use with caution in the presence of hypertension, cardiovascular abnormalities, hyperglycemia (diabetes), hyperthyroidism, ocular infection or injury and when other medications are being used.

Patient Information

Patients should be advised to discontinue the drug and consult a physician if relief is not obtained within 48 hours of therapy, if irritation, blurring, or redness persists or increases, or if symptoms of systemic absorption occur, i.e., dizziness, headache, nausea, decrease in body temperature, or drowsiness.

To prevent contaminating the dropper tip and solution, do not touch the eyelids or the surrounding area with the dropper tip of the bottle. If solution changes color or becomes cloudy, do not use.

Drug Interactions

Concurrent use of maprotiline or tricyclic antidepressants and naphazoline may potentiate the pressor effect of naphazoline. Patients under therapy with MAO inhibitors may experience a severe hypertensive crisis if given a sympathomimetic drug. (See WARNINGS).

Pregnancy Category C

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

Nursing Mothers

If is not known whether naphazoline is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when naphazoline is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children have not been established. See “WARNINGS” and “CONTRAINDICATIONS”.

ADVERSE REACTIONS

Ocular

Mydriasis, increased redness, irritation, discomfort, blurring, punctate keratitis, lacrimation, increased intraocular pressure.

Systemic

Dizziness, headache, nausea, sweating, nervousness drowsiness, weakness, hypertension, cardiac irregularities, and hyperglycemia.

DOSAGE AND ADMINISTRATION

Instill one or two drops in the conjunctival sac(s) every three to four hours as needed.

HOW SUPPLIED

VASOCON REGULAR (naphazoline hydrochloride ophthalmic solution USP, 0.1%): 15 mL plastic squeeze bottle with dropper tip. NDC 58768-844-15 To be dispensed only in original, unopened container. Store at controlled room temperature 15°-30°C (59°-86°F).

CAUTION: Federal law prohibits dispensing without prescription.

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Ophthalmics®

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Atlanta, Georgia 30155

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VASOCON

naphazoline hydrochloride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:58768-844
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
naphazoline hydrochloride (UNII: MZ1131787D) (naphazoline - UNII:H231GF11BV)		1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
benzalkonium chloride ()	
edetate disodium (UNII: 7FLD91C86K)	
hydrochloric acid (UNII: QTT17582CB)	
polyethylene glycol 8000 ()	
polyvinyl alcohol ()	
water (UNII: 059QF0KO0R)	
sodium chloride (UNII: 451W47IQ8X)	
sodium hydroxide (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58768-844-15	15 mL in 1 BOTTLE, DROPPER		

Labeler - CIBA Vision

Revised: 8/2006 CIBA Vision