

PI YEN CHIN- naphazoline hydrochloride solution/ drops
International Nature Nutraceuticals

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients

Naphazoline Hydrochloride: 0.01%

Purpose: Eye redness reliever

Uses

Temporarily relieves redness due to minor irritation of eye

Warnings: For external use only

Do not use if allergic to any of the ingredients.

If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor.

Ask a doctor before use if you have narrow angle glaucoma.

Overuse of this product may produce increased redness of the eye.

If solution changes color or becomes cloudy, do not use.

When using this product pupils may become enlarged temporarily

Keep out of reach of Children

Directions:

1 to 2 drops instilled into the affected eye(s) 1 to 4 times a day. Do not use for children under the age of 6.

Other Information

To prevent contaminating the dropper tip and solution, care should be taken not to touch any surface, the eyelids, or surrounding area with the dropper tip of the bottle. Replace cap after using. Keep bottle tightly closed when not in use and store in a cool dry place. Do not use if seal is broken.

Inactive Ingredients

Boric Acid, Sodium Borate, Disodium Edetate, Thimerosal, Distilled Water

Packaging



PI YEN CHIN

naphazoline hydrochloride solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51367-008
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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NAPHAZOLINE HYDROCHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV)	NAPHAZOLINE HYDROCHLORIDE	1 mg
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Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
THIMEROSAL (UNII: 2225PI3MOV)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51367-008-10	1 in 1 BOTTLE, DROPPER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	07/01/1985	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	07/01/1985	

Labeler - International Nature Nutraceuticals (006106879)

Establishment

Name	Address	ID/FEI	Business Operations
Hubei Kangzheng Pharmaceutical Co., Ltd		530031426	manufacture(51367-008)

Revised: 7/2017

International Nature Nutraceuticals