

NDA 20-485/S-009 Visine®-A® Eye Drops (pheniramine maleate 0.3% & naphazoline hydrochloride 0.025%)  
 Ophthalmic Solution  
 Response to FDA Comments-COMLETE RESPONSE



(b) (4)

SECONDARY PACKAGE

COMPANY CONFIDENTIAL

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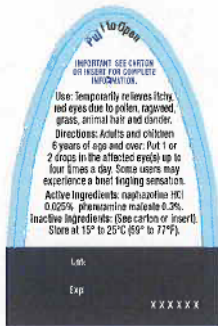


PRIMARY PACKAGE - FRONT LABEL

COMPANY CONFIDENTIAL

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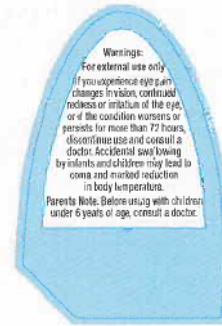
NDA 20-485/S-009 Vtsine®-A® Eye Drops (pheniramine maleate 0.3% & naphazoline hydrochloride 0.025%)  
Ophthalmic Solution  
Response to FDA Comments-COMplete RESPONSE



TOP PLY FRONT



TOP PLY BACK (OPENED)



BASE PLY FRONT



(b) (4)

NDA 20-485/S-009 Visine®-A® Eye Drops (pheniramine maleate 0.3% & naphazoline hydrochloride 0.025%)  
 Ophthalmic Solution  
 Response to FDA Comments-COMplete RESPONSE

PLEASE READ CAREFULLY AND KEEP THIS INSERT FOR FUTURE REFERENCE

**Visine-A®** *Sterile*

PHENIRAMINE MALEATE 0.3%  
 NAPHAZOLINE HCl 0.025%  
 ANTIHISTAMINE + REDNESS  
 RELIEVER EYE DROPS  
**MULTI-ACTION  
 EYE  
 ALLERGY**  
 Relief

Clinically proven to relieve  
 itchy, red, allergy eyes

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredients</b> Naphazoline HCl 0.025% Pheniramine maleate 0.3%	<b>Purpose</b> Redness reliever Antihistamine	<b>Stop use and ask a doctor if</b> • you feel eye pain • changes in vision occur • redness or irritation of the eyelids • condition worsens or lasts more than 72 hours	
<b>Use</b> Temporarily relieves itchy, red eyes due to: • pollen • ragweed • grass • animal hair and dander		<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away. Accidental swallowing by infants and children may lead to coma and marked reduction in body temperature.	
<b>Warnings</b> For external use only <b>Do not use if you are sensitive to any ingredient in this product.</b> <b>Ask a doctor before use if you have</b> • heart disease • high blood pressure • narrow angle glaucoma • trouble urinating due to an enlarged prostate gland		<b>Directions</b> • adults and children 6 years of age and over: put 1 or 2 drops in the affected eye(s) up to four times a day • children under 6 years of age: consult a doctor	
<b>When using this product</b> • pupils may become enlarged temporarily • do not touch tip of container to any surface to avoid contamination • replace cap after each use • remove contact lenses before using • do not use if this solution changes color or becomes cloudy • overuse may cause more eye redness		<b>Other information</b> • use before expiration date marked on the carton or bottle • some users may experience a brief tingling sensation • store at 15° to 25°C (59° to 77°)	
		<b>Inactive ingredients</b> benzalkonium chloride, boric acid, edetate disodium, purified water, sodium borate, sodium hydroxide and/or hydrochloric acid	
		<b>Questions?</b> 888-734-7648, or Outside US, dial collect 215-273-8755	

Dist: Johnson & Johnson Healthcare Products  
 Division of McNEIL-PPC, Inc., Skillman, NJ 08558 USA  
 Made in Belgium © McNEIL-PPC, Inc. 2012 www.visine.com

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**Visine-A**<sup>®</sup>

ANTIHISTAMINE + REDNESS  
 RELIEVER EYE DROPS  
 MULTI-ACTION  
**EYE ALLERGY**  
 Relief



VALUE TWIN PACK

VALUE TWIN PACK

**Drug Facts (continued)**

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. Accidental swallowing by infants and children may lead to coma and marked reduction in body temperature.

**Directions**

- adults and children 6 years of age and over: put 1 or 2 drops in the affected eye(s) up to four times a day
- children under 6 years of age: consult a doctor

**Other information**

- some users may experience a brief tingling sensation
- store at 15° to 25°C (59° to 77°F)

**Inactive ingredients**

benzalkonium chloride, boric acid, edetate disodium, purified water, sodium borate, sodium hydroxide and/or hydrochloric acid

**Questions?**

888-734-7648; or Outside US, dial collect 215-273-8755

**Visine-A**<sup>®</sup>

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 NAPHAZOLINE HCl 0.025%  
 ANTIHISTAMINE + REDNESS  
 RELIEVER EYE DROPS  
 MULTI-ACTION  
**EYE ALLERGY**  
 Relief

Clinically proven to relieve itchy, red, allergy eyes

2 BOTTLES:  
 1/2 FL. OZ. (15mL) each  
 NET 1 FL. OZ. (30mL)

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 1/2 FL. OZ. (15mL) each  
 NET 1 FL. OZ. (30mL)

Caution: Do not use if VISINE<sup>®</sup> imprinted neckband on bottle is broken or missing.

**Drug Facts**

Active ingredients	Purpose
Naphazoline HCl 0.025%	Redness reliever
Pheniramine maleate 0.3%	Antihistamine

**Use** temporarily relieves itchy, red eyes due to:  
 • pollen • ragweed • grass • animal hair and dander

**Warnings**

**For external use only**

Do not use if you are sensitive to any ingredient in this product

**Ask a doctor before use if you have**

- heart disease
- high blood pressure
- narrow angle glaucoma
- trouble urinating due to an enlarged prostate gland

**When using this product**

- pupils may become enlarged temporarily
- do not touch tip of container to any surface to avoid contamination
- replace cap after each use
- remove contact lenses before using
- do not use if this solution changes color or becomes cloudy
- overuse may cause more eye redness

**Stop use and ask a doctor if**

- you feel eye pain
- changes in vision occur
- redness or irritation of the eye lasts
- condition worsens or lasts more than 72 hours

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LOT:

EXP:



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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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JOEL SCHIFFENBAUER  
12/18/2012