EMERGENCY EYE WASH, PW, STERILE STER-AIDE- water for solution Asept Pak, Inc.

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.

Emergency Eye Wash, PW, Sterile 15 ml Ster-Aide

Drug Facts

Active Ingredients

Purified water 99%

Purpose

Eyewash

Indication

For flushing the eyes to help relieve irritation, discomfort, burning, stinging or itching by removing loose foreign material and air pollutants (smog or pollen).

Warnings

For external use only.

- Obtain immediate medical treatment for all open wounds in or near the eye
- To avoid contamination, do not touch tip of container to any surface
- Do not reuse
- Discard vial after use

Do not use if:

- Solution changes color or becomes cloudy
- With contact lenses
- If vial is open or seal is broken.

Stop use and consult a doctor if you experience:

- Eye pain
- Changes in vision
- Continued redness or irritation of the eye or if the condition worsens or persists.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Twist top to remove
- Wash the affected eye(s) as needed
- Control rate of flow by pressure on the vial
- If necessary, continue flushing with emergency eyewash or shower

Inactive Ingredients

- Boric Acid
- Sodium Borate
- Sodium Chloride
- Sorbic Acid

Questions

Call SterRx at (518) 651-2026

NDC 51997-035-05

Store at 41-95°F (5-35°C)

Manufactured by SterRx 64 West St., Malone, NY 12953

PRINCIPAL DISPLAY PANEL - 15 ml Vial Label

TAMPER-EVIDENT CAP DO NOT USE IF TWIST-OFF TOP IS BROKEN OR MISSING

STERILE

EYE WASH

FIRST AID TREATMENT FOR EYE

1/2 FL OZ (15 ml)

Store at 41-95°F (5-35°C) Manufactured by SterRx 64 West St., Malone, NY 12953

5mm Clear Area - No Graphics

Drug Facts (continued)

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EMERGENCY EYE WASH, PW, STERILE STER-AIDE

water for solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51997-035

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Water (UNII: 059QF0KO0R) (Water - UNII:059QF0KO0R)	Water	14.85 mL in 15 mL

Inactive Ingredients			
Ingredient Name	Strength		
Boric Acid (UNII: R57ZHV85D4)			
Sodium Borate (UNII: 91MBZ8H3QO)			
Sodium Chloride (UNII: 451W47IQ8X)			
Sorbic Acid (UNII: X045WJ989B)			

Product Characteristics			
Color	WHITE (Clear)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:51997-035-05	15 mL in 1 VIAL, SINGLE-USE			
2	NDC:51997-035-10	30 mL in 1 VIAL, SINGLE-USE			
3	NDC:51997-035-15	120 mL in 1 VIAL, SINGLE-USE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part349	09/10/2012	

Labeler - Asept Pak, Inc. (005245137)

Establishment			
Name	Address	ID/FEI	Business Operations
Asept Pak, Inc.		005245137	MANUFACTURE(51997-035)

Revised: 8/2012 Asept Pak, Inc.