PLUM PH NEUTRAL EMERGENCY EYEWASH/EMERGENCY EYEWASH DUO/EMERGENCY EYEWASH SHOWER ISS USA - water liquid Plum A/S

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 ingredient

Purified water 95.1%

Purpose

Emergency eyewash

Uses

For rinsing the eyes to reduce risk of severe injury caused by acid or alkali

Warnings

For external use only

Do not use

- for injection
- for intraocular surgery
- internally
- If solution changes color or becomes cloudy.

When using this product

- avoid contamination
- do not reuse. Once opened, discard.

Ask a doctor if you have

- eye pain
- changes in vision
- redness or irritation of the eye after use
- an injury caused by alkali

Keep out of reach of children

• If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- do not dilute solution or reuse bottle
- use only unopened bottle
- to open, twist cap in the direction of the arrow
- avoid contamination of the integrated eyecup
- place integrated eyecup over affected eye(s)
- tilt head backward
- open eyelid(s) wide
- control rate of flow by pressure on bottle
- thoroughly bathe eye(s) with solution
- allow solution to flow away from eye(s)
- rinse until the bottle is empty and continue rinsing with Plum Emergency Eyewash until you reach a doctor
- continue rinsing with water if necessary
- obtain medical treatment.

Other information

- not for use as a contact lens solution
- do not use after bottle expiration
- store at room temperature, 5° to 35° C (41° to 95°F)

Inactive ingredients

Sodium phosphate dibasic, Monopotassium phosphate

Questions or Comments?

Call toll-free number 1-844-405-7233

Imported and distributed by

Innovative Safety Supply Inc., 304 Edson St., Saskatoon, Saskatchewan S7J 0P9, Canada (CAN)

Principal Display Panel

NDC: 42659-022-20

Plum

pH Neutral

Emergency Eyewash

Compliance: ANSI/ISEA Z358.1-2014

(As Personal Eyewash Only)

plum

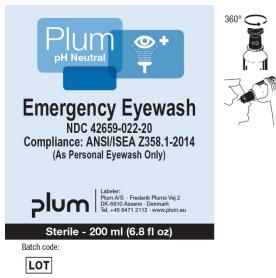
Labeler: Plum A/S - Frederik plums Vej 2

DK - 5610 Assens - Denmark

Tel. +45 6471 2112

www.plum.eu

Sterile - 200 ml (6.8 fl oz)





Drug Facts

Active ingredient

Purified water 95.1%

Purpose

Uses For rinsing the eyes to reduce risk of severe injury caused by acid or alkali

Warnings For external use only

Do not use

• for injection • for intraocular surgery • internally • if solution changes color or becomes cloudy.

When using this product • avoid contamination • do not reuse. Once opened, discard.

Ask doctor if you have

• eye pain • changes in vision • redness or irritation of the eye after use • an injury caused by an alkali

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

Directions • do not dilute solution or reuse bottle

- · use only unopened bottle
- . to open, twist cap in the direction of the arrow
- avoid contamination of integrated eyecup
 place integrated eyecup over affected eye(s)
 tilt head backward

- open eyelid(s) wide
 control rate of flow by pressure on bottle
- thoroughly bathe eye(s) with solutionallow solution to flow away from eye(s)
- rinse until the bottle is empty and continue rinsing with Plum Emergency Eyewash until you reach a
- continue rinsing with water if necessary
 obtain medical treatment

Other Information • not for use as a contact lens solution

- do not use after bottle expiration - store at room temperature, 5° to 35° C (41° to 95° F)

Inactive Ingredients sodium phosphate dibasic, monopotassium phosphate

Questions or Comments? Call toll-free number 1-844-405-7233

Imported and distributed by: Innovative Safety Supply Inc, 304 Edson St., Saskatoon, Saskatchewan S7J 0P9, Canada (CAN)

NDC: 42659-022-22

Plum

pH Neutral DUO

Emergency Eyewash

Compliance: ANSI/ISEA Z358.1-2014

(As Personal Eyewash Only)

plum

Labeler: Plum A/S - Frederik plums Vej 2

DK - 5610 Assens - Denmark

Tel. +45 6471 2112

www.plum.eu

Sterile - 500 ml (16.9 fl oz)





Imported and distributed by: Innovative Safety Supply Inc, 304 Edson St., Saskatoon, Saskatchewan S7J OP9, Canada (CAN)

LOT

NDC: 42659-022-24

Plum

pH Neutral

Emergency Eyewash Shower

Compliance: ANSI/ISEA Z358.1-2014

(As Personal Eyewash Only)

plum

Labeler: Plum A/S - Frederik plums Vej 2

DK - 5610 Assens - Denmark

Tel. +45 6471 2112

www.plum.eu

Sterile - 1000 ml (33.8 fl oz)





Drug Facts

Active ingredient
Purpose
Purlined water 95.1%.

Uses For insing the eyes to reduce risk of severe injury caused by acid or alkali.

Warnings
For external use • for injection • for intraocular surgery • internally • if solution changes color or becomes cloudy.

When using this product • avoid contamination • do not reuse. Once opened, discard.

Ask doctor if you have • eye pain • changes in vision • redness or irritation of the eye after use • an injury caused by an alkali

Keep out of reach of children • if is swallowed, get medical help or contact a Poison Control Center right away

Directions • do not dilute solution or reuse bottle

use only unopened bottle
• use only unopened bottle
• to open, twist cap in the direction of the arrow
avid contamination of integrated eyecup
p place integrated eyecup over affected eye(s)
• iith head backward
• open eyelicid or integrated eyecup
• place integrated eyecup over affected eye(s)
• control rate of flow by pressure on bottle

Other Information
not for use as a contact lens solution • do not use after bottle expiration • store at room temperature, 5° to 35° C (41° to 95° F).

Inactive Ingredients sodium phosphate dibasic, monopotassium phosphate

Questions or Comments? Call toil-free number 1-844-405-7233

Imported and distributed by: Innovative Safety Supply Inc, 304 Edson St., Saskatoon, Saskatchewan S7J DP9, Canada (CAN)

PLUM PH NEUTRAL EMERGENCY EYEWASH/EMERGENCY EYEWASH DUO/EMERGENCY EYEWASH SHOWER ISS USA

water liquid

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:42659-022

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Water (UNII: 059QF0KO0R) (Water - UNII:059QF0KO0R)	Water	95.1 mL in 100 mL

Inactive Ingredients

mactive ingredients				
Ingredient Name	Strength			
Sodium Phosphate, Dibasic (UNII: GR686LBA74)				
Potassium Phosphate, Monobasic (UNII: 4J9FJ0HL51)				

Packaging # Item Code Package Descriptio

ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:42659-022-20	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2016	
l	2	NDC:42659-022-21	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2016	
l	3	NDC:42659-022-22	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2016	
	4	NDC:42659-022-23	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2016	

5 NDC:42659-022-24 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product 06/13/2016

Marketing Information

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	06/13/2016	

Labeler - Plum A/S (305299489)

Establishment

Name	Address	ID/FEI	Business Operations
Plum A/S	/S 305299		label(42659-022)

Esta			

Name	Address	ID/FEI	Business Operations

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Holopack Verpackungstechnik GmbH	343390324	Manufacture(42659-022)

Revised: 6/2016 Plum A/S