

EQUATE DAY AND NIGHT RESTORE TEARS- mineral oil, white petrolatum and carboxymethylcellulose sodium

Wal-Mart Stores, 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.

Equate Day and Night Restore Tears

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Equate

Day & Night Restore Tears

15mL & 3.5g

NDC 49035-883-59

Restore PM Lubricant Eye Ointment NDC# 49035-191-50

Drug Facts

Active ingredients

Mineral Oil 42.5% and White Petrolatum 57.3%

Purpose

Lubricant

Uses

- for the temporary relief of burning, irritation and discomfort due to dryness of the eye.
- exposure to wind or sun
- may be used as a protectant against further irritation.

Warnings

- **For use in the eyes only.**
- Retain outer carton for full product drug facts.

When using this product

- avoid contamination, do not touch tip of container to any surface.
- replace cap after use.

Stop use and ask a doctor if

- you experience eye pain, changes in vision, continued redness or irritation of the eye.
- the condition worsens or persists for more than 72 hours.

If pregnant or breast feeding,

ask a health professional before use.

Keep this and all drugs out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- pull down lower lid of eye and apply a small amount (one-fourth inch) of ointment to the inside of the eyelid, every 3-4 hours or as directed by doctor.

Other information

- Do not use if bottom ridge of tube cap is exposed, and if imprinted seals on side flaps are not intact and completely legible • store at room temperature 15°-30°C (59°-86°F)
- store away from heat
- keep from freezing
- see crimp of tube or box for lot number and expiration date

Inactive ingredients

lanolin alcohols

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Equate

Day & Night Restore Tears

15mL & 3.5g

NDC 49035-883-59

Restore Tears Lubricant Eye Drops NDC 49035-189-13

Drug Facts***Active ingredients***

Carboxymethylcellulose Sodium 0.5%

Purpose

Eye Lubricant

Uses

- for the temporary relief of burning, irritation and discomfort due to dryness of the eye.
- exposure to wind or sun
- may be used as a protectant against further irritation.

Warnings

- **For use in the eyes only.**
- Retain outer carton for full product drug facts.

Do not use

- if this product changes color or becomes cloudy.

When using this product

- avoid contamination, do not touch tip of container to any surface.
- replace cap after use.

Stop use and ask a doctor if

- you experience eye pain, changes in vision, continued redness or irritation of the eye.
- the condition worsens or persists for more than 72 hours.

Keep this and all drugs out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- Instill 1 or 2 drops in the affected eye(s) as needed.

Other information

- Do not use if imprinted seal on cap is torn, broken or missing
- store at room temperature 15°-30°C (59°-86°F)
- keep tightly closed

Inactive ingredients

Boric Acid, calcium chloride, magnesium chloride, potassium chloride, sodium borate, water for injection. Vanish® (Stabilized Peroxycomplex System as a preservative). May contain hydrochloric acid and/or sodium hydroxide to adjust pH.

PRINCIPAL DISPLAY PANEL

NDC 49035-883-59

Equate

Day & Night

Restore Tears

15mL & 3.5g



EQUATE DAY AND NIGHT RESTORE TEARS

mineral oil, white petrolatum and carboxymethylcellulose sodium kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-883
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-883-59	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	06/01/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, DROPPER	15 mL
Part 2	1 TUBE	3.5 g

Part 1 of 2

RESTORE TEARS LUBRICANT EYE

carboxymethylcellulose sodium solution/ drops

Product Information

Route of Administration OPTHALMIC

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) (CARBOXYMETHYLCELLULOSE - UNII:05JZI7B19X)	CARBOXYMETHYLCELLULOSE SODIUM	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
WATER (UNII: 059QF0KO0R)	
CHLORINE DIOXIDE (UNII: 8061YMS4RM)	
POLYHEXANIDE (UNII: 322U039GMF)	

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
May contain	HYDROCHLORIC ACID (UNII: QTT17582CB)	
May contain	SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part349	06/01/2018	

Part 2 of 2

RESTORE PM LUBRICANT EYE

mineral oil, petrolatum ointment

Product Information

Route of Administration OPTHALMIC

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	425 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	573 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part349	06/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part349	06/01/2018	

Labeler - Wal-Mart Stores, Inc. (051957769)

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Wal-Mart Stores, Inc.