

**DORAMA DRY AID EYE DROPS- povidone, propylene glycol solution
Sato Pharmaceutical Co., Ltd.**

Dorama Dry Aid Eye Drops

Active ingredients

Povidone 0.68%

Propylene glycol 0.3%

Purpose

Povidone Lubricant

Propylene glycolLubricant

Uses

- temporarily relieves burning and irritation due to dryness of the eye
- protects against further irritation or to relieve dryness of the eye

Warnings

For external use only

When using this product

To avoid contamination

- do not touch tip of container to any surface
- replace cap after each use
- do not use if solution changes color or becomes cloudy
- remove contact lenses before using

Stop use and ask a doctor if

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

Keep out of reach of children.

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

Directions

- put 1 or 2 drops in the affected eye(s) as needed
- tightly snap on cap to seal

Other information

- do not freeze

Inactive ingredients

benzalkonium chloride, boric acid, calcium chloride, edetate disodium, menthol, polysorbate 80, purified water, sodium borate, sodium chloride.

Box label



DORAMA DRY AID EYE DROPS

povidone, propylene glycol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49873-503
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	0.3 g in 100 mL
POVIDONE (UNII: FZ989GH94E) (POVIDONE - UNII:FZ989GH94E)	POVIDONE	0.68 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
BORIC ACID (UNII: R57ZHV85D4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-503-01	1 in 1 CARTON	01/13/2022	06/30/2025
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 Drug	M018	01/13/2022	06/30/2025

Labeler - Sato Pharmaceutical Co., Ltd. (690575642)

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Co., Ltd.		715699133	manufacture(49873-503) , pack(49873-503) , label(49873-503)