

IMPROVUE LUBRICANT- hypromellose 2208 (15000 mpa.s) solution/ drops
Oculus Surgical, 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.

ImproVue®
Ophthalmic Lubricant Drops

Drug Facts

Active Ingredients

Hypromellose (1.7%)

Purpose

Ophthalmic Lubricant

Indications

- For the temporary relief of burning and irritation due to dryness of the eye.
- For use as a lubricant to prevent further irritation or to relieve dryness of the eye.

Warnings

- For external use only.
- To avoid contamination do not touch tip of container or applicator to any surface.
- Do not reuse. Once opened, discard.

Stop use and ask a doctor if

- If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor.
- If solution changes color or becomes cloudy, do not use.

Keep out of reach of children

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

Directions

- Remove cap from syringe and screw on applicator tip.
- Instill 1 or 2 drops in the affected eye(s) as needed.

Other Information

- Do not use if pouch is damaged or has been previously opened.
- Protect from freezing
- Store at or below 25°C (77°F)

Inactive Ingredients

Calcium chloride dihydrate, hydrochloric acid¹, magnesium chloride hexahydrate, potassium chloride, purified water, sodium acetate trihydrate, sodium chloride, sodium citrate dihydrate, and sodium hydroxide¹

¹ May contain one or more of these ingredients for pH adjustment

Questions or Comments?

(855) 734-2466 or (772) 236-2622 or log onto www.oculussurgical.com

PRINCIPAL DISPLAY PANEL - 6 Pouch Carton

ImproVue®

Ophthalmic Lubricant Drops

- Sterile
- Preservative-free
- Single use, disposable container

Contains:

6 Pouches, each Pouch containing
1 Single Use Syringe, 0.07 fl oz (2 ml)
1 Single Use Applicator Tip

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Ophthalmic Lubricant Drops

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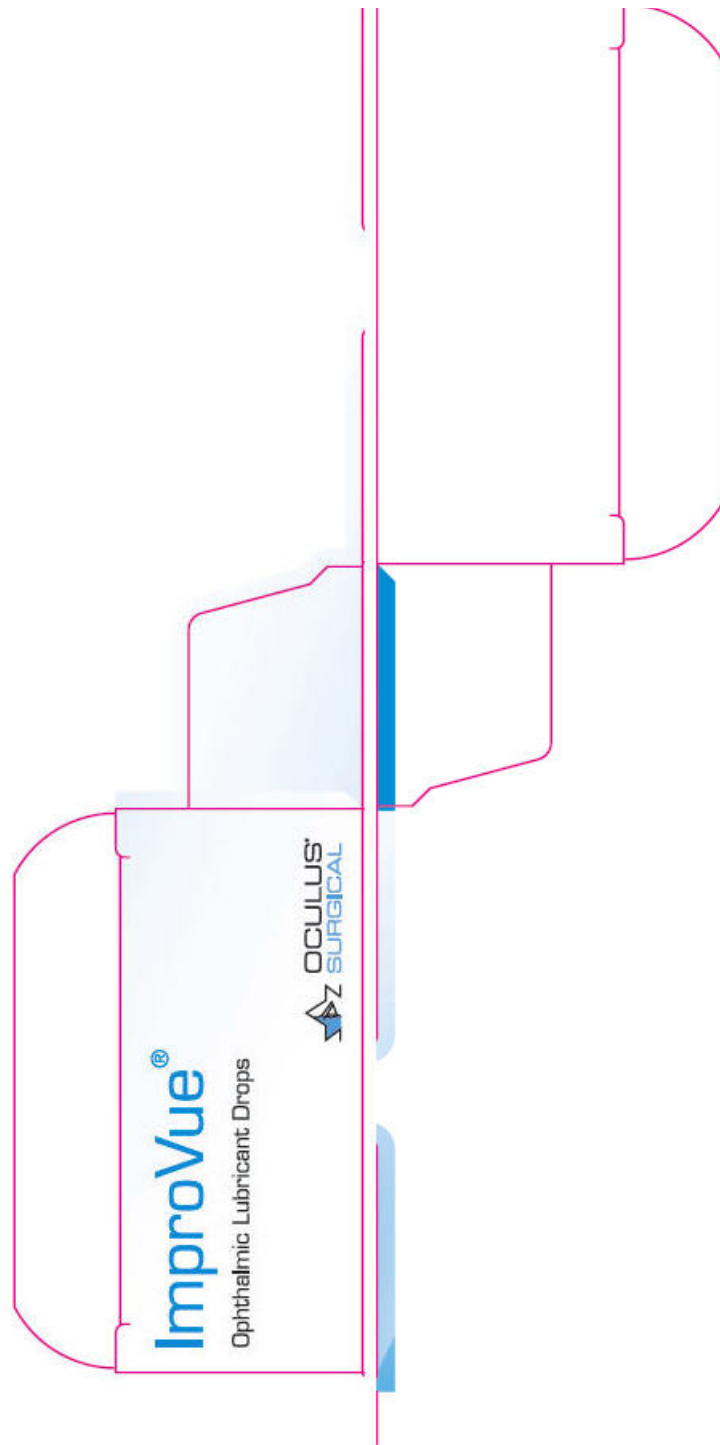
Drug Facts	Purpose Ophthalmic Lubricant
Active Ingredients Hydroxyethylcellulose (1.7%)	
Indications	<ul style="list-style-type: none"> ■ For the temporary relief of burning and irritation due to dryness of the eye. ■ For use as a lubricant to prevent further irritation or to relieve dryness of the eye.
Warnings	<ul style="list-style-type: none"> ■ For external use only. ■ To avoid contamination do not touch tip of container or applicator to any surface. ■ Do not reuse. Once opened, discard.
Stop use and ask a doctor if	<ul style="list-style-type: none"> ■ If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor. ■ If solution changes color or becomes cloudy, do not use.
Keep out of reach of children	<ul style="list-style-type: none"> ■ If swallowed, get medical help or contact a Poison Control Center right away.
Directions	<ul style="list-style-type: none"> ■ Remove cap from syringe and screw on applicator tip. ■ Instill 1 or 2 drops in the affected eye(s) as needed.
Other Information	<ul style="list-style-type: none"> ■ Do not use if pouch is damaged or has been previously opened. ■ Protect from freezing ■ Store at or below 25°C (77°F)
Inactive Ingredients	Calcium chloride dihydrate, hydrochloric acid*, magnesium chloride hexahydrate, potassium chloride, purified water, sodium acetate trihydrate, sodium chloride, sodium citrate dihydrate, and sodium hydroxide* * May contain one or more of these ingredients for pH adjustment
Questions or Comments?	(855) 734-2468 or (772) 236-2622 or log onto www.oculussurgical.com

Manufactured for:
 OCULUS[®]
 SURGICAL
 Port St. Lucie, FL 34986 USA



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 411A

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IMPROVUE LUBRICANT

hypromellose 2208 (15000 mpa.s) solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62144-5510
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2) (HYPROMELLOSE 2208 (15000 MPA.S) - UNII:Z78RG6M2N2)		HYPROMELLOSE 2208 (15000 MPA.S)	17 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
Calcium Chloride (UNII: M4I0D6VV5M)				
Hydrochloric Acid (UNII: QTT17582CB)				
Magnesium Chloride (UNII: 02F3473H9O)				
Potassium Chloride (UNII: 660YQ98I10)				
Water (UNII: 059QF0KO0R)				
Sodium Acetate (UNII: 4550K0SC9B)				
Sodium Chloride (UNII: 451W47IQ8X)				
Trisodium Citrate Dihydrate (UNII: B22547B95K)				
Sodium Hydroxide (UNII: 55X04QC32I)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62144-5510-5	6 in 1 CARTON	06/25/2014	
1		1 in 1 POUCH		
1		2 mL in 1 SYRINGE, PLASTIC; 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	06/25/2014		

Labeler - Oculus Surgical, Inc. (015409582)

Establishment

Name	Address	ID/FEI	Business Operations
OASIS Medical, Inc.		194121018	MANUFACTURE(62144-5510)

Establishment

Name	Address	ID/FEI	Business Operations
OASIS Medical, Inc.		024362989	PACK(62144-5510)