

REJUVADERM MEDISPA SUNSCREEN - octinoxate, octisalate, zinc oxide lotion
Ellen H Frankle MD 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.

Rejuvaderm Medispa Sunscreen

Active Ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Octisalate 2%	Sunscreen
Zinc Oxide 7.5%	Sunscreen

Uses

- Helps prevent sunburn caused by UVA/UVB exposure
- Provides high UVB protection

Warnings

For external use only

- UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.
- Stop use and ask a doctor if skin rash occurs.
- Keep out of reach of children.
- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply at least every 2 hours and after towel drying, swimming, or perspiring
- Children under 6 months of age: ask a doctor
- Reapply to dry skin as needed or after towel drying, swimming or sweating.

Inactive Ingredients

Water USP, Isopropyl Myristate, Octyldoceyl Neopentanoate, Caprylic/Capric Triglyceride, Cetearyl alcohol, Polysorbate 60, Diethanolamine Cetyl Phosphate, Hyaluronic Acid, Polyether-1, Galactarabinan, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Triethoxycaprylsilane, Sodium Hydroxide, Citric Acid, Phenoxyethanol, Methylparaben, Propylparaben, Disodium EDTA.



SUNSCREEN LOTION
SPF 40

4 FL. OZ (120 ML)

401.944.SKIN
WWW.RISKINDOC.COM
WWW.REJUVADERM.MEDISPA.COM

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5%.....	Sunscreen
Octisalate 2%.....	Sunscreen
Zinc Oxide 7.5%.....	Sunscreen

Uses

- Helps prevent sunburn caused by UVA/UVB exposure.
- Provides high UVB protection.

Warnings

For external use only

- UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.
- Stop use and ask a doctor if skin rash occurs.
- Keep out of reach of children.
- If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ Apply at least every 2 hours and after towel drying, swimming, or perspiring. ■ Children under 6 months of age: ask a doctor. ■ Reapply to dry skin as needed or after towel drying, swimming or sweating.

Inactive Ingredients Water USP, Isopropyl Myristate, Octyldoecyl Neopentanoate, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Polysorbate 60, Diethanolamine Cetyl Phosphate, Hyaluronic Acid, Polyether-1, Galactoarabinan, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Triethoxycaprylylsilane, Sodium Hydroxide, Citric Acid, Phenoxyethanol, Methylparaben, Propylparaben, Disodium EDTA.

Distributed by:
Dr. Ellen H. Frankel
REJUVADERM MEDISPA
750 Reservoir Ave, Cranston, RI 02910
61771L Made in U.S.A.

Rejuvaderm Medispa

Reawaken the essence that is you

Sunscreen Lotion SPF 40

4 fl oz (120 ml)

401.944skin

www.riskindoc.com

ww.rejuvadermmedispa.com

REJUVADERM MEDISPA SUNSCREEN

octinoxate, octisalate, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51325-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	9 mL in 120 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	2.4 mL in 120 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	9 mL in 120 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51325-100-01	120 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2010	

Labeler - Ellen H Frankle MD Inc (603208240)

Revised: 8/2010

Ellen H Frankle MD Inc