

REJUVADERM MEDISPA BODY - octinoxate, octisalate, oxybenzone 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 Body

Active Ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Octisalate 5.0%	Sunscreen
Oxybenzone 3.0%	Sunscreen

Uses

Helps prevent sunburn.

Higher SPF gives more sunburn protection.

Provides moderate protection against sunburn.

Warnings

For external use only

When using this product

- keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

- rash or irritation develops and lasts.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Inactive Ingredients Water (Aqua), Glycolic Acid, C12-15 Alkyl Benzoate, Cyclomethicone, Glyceryl Stearate, Glycerin, Ammonium Hydroxide, PEG-150 Stearate, Polyacrylamide, Cetyl alcohol, Cetearyl Alcohol, Butyrospermum Parkii (shea butter), Cholesterol, Phenoxyethanol, Dimethiconol, C13-14 Isoparaffin, Methylparaben, Xanthan gum, cetearyl glucoside, Disodium EDTA, Tocopheryl acetate, Laureth-7

Directions:

- Apply daily to cleansed body skin or as directed by your physician; avoid face.
- Apply generously before sun exposure and as needed.
- Children under 6 months of age: ask a doctor.

Other Information

Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin cancer, and harmful effects of the sun.

This product is not intended for sunbathing.

Drug Facts	
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Drug Facts (Continued)	
Directions	■ Apply daily to cleansed body skin or as directed by your physician; avoid face. ■ Apply generously before sun exposure and as needed. ■ Children under 6 months of age: ask a doctor.
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Rejuvaderm Medispa
Reawaken the essence that is you
Body Lotion
SPF 15
12 fl oz (355 ml)
401944skin

REJUVADERM MEDISPA BODY

octinoxate, octisalate, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51325-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	26.625 mL in 355 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	17.75 mL in 355 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	10.65 mL in 355 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51325-200-02	355 mL in 1 BOTTLE		

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)