RECLARX MOISTURE SHIELD- octocrylene and avobenzone cream NBC Aesthetics, LLC

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.

Drug Facts

Active Ingredients

Octocrylene 7%, Butyl Methoxydibenzoylmethane 2%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- if used as directed with other sun protection measures (see *Directions*) decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only.

Do not use on damage or broken skin.

When using this product, keep out of eyes. Rinse with water to remove.

Stop use and ask doctor if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply liberally to face and neck after Step 3 at least 15 minutes before sun exposure.

- Use a water resistant sunscreen if swimming or sweating
- reapply immediately after towel drying
- at least every 2 hours.

Sun Protection Measures:

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including

- limit time in the sun, especially from 10am-2pm
- wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: Ask a doctor.

Other Information

Protect this product from excessive heat and direct sun.

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Bambusa Vulgaris (Bamboo) Leaf/Stem Extract, Butylene Glycol, Butyrospermum Parkii (Shea Butter), Calendula Officinalis Seed Oil, Caprylic/Capric Triglyceride, Caprylyl Glycol, Carbomer, Cera Alba (Beeswax), Cetyl Alcohol, Dimethicone, Fragrance (Perfume), Glycerin, Glyceryl Stearate SE, Isopropyl Myristate, Lavandula Angustifolia (Lavender) Extract, Maris Aqua (Dead Sea Water), Nordihydroguaiaretic Acid, Peg-40 Stearate, Olea Europaea (Olive) Fruit Oil, Oleanolic Acid, Peg-60 Almond Glycerides, Persea Gratissima (Avocado) Oil, Phenoxyethanol, Rosa Canina Fruit, Rosmarinus Officinalis (Rosemary) Leaf Extract, Salicylic Acid, Simmondsia Chinensis (Jojoba) Seed Oil, Theobroma Cacao (Cocoa) Seed Butter, Triethylene Glycol, Vitis Vinifera (Grape) Seed Oil, Water.

Questions or Comments:

Call 1-800-397-7191, Mon-Fri

Principal Display Panel - Bottle Label

Reclarx_{TM} BD

Blemish-Defying Regimen

All Skin Types

Moisture Shield

Sunscreen

Broad Spectrum

SPF 15

STEP

4

AM/PM

Locks In moisture and provides UVA/UVB protection against the elements

DERMATOLOGIST TESTED • NOT TESTED ON ANIMALS

Exclusively distributed by: NBC Aesthetics, LLC • 23715 Mercantile Road • Beachwood, Ohio 44122 • info@reclarx.com • www.reclarx.com



All Skin Types

Moisture Shield

Sunscreen **Broad Spectrum SPF 15**



AM/PM

Locks in moisture and provides UVA/UVB protection against the elements

1.69 FL. OZ. (50ml)

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SKU: RMO50MS7131

Made in Israel

RECLARX MOISTURE SHIELD

octocrylene and avobenzone cream

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r roa			10117	

Route of Administration

KERADIGM LABS

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61402-7131

TOPICAL

Active Ingredient/Active Mojety

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Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	7 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISO PRO PYL MYRISTATE (UNII: 0 RE8K4L NIS)	

GLYCERIN (UNII: PDC6 A3C0 O X)
CALENDULA OFFICINALIS SEED OIL (UNII: 9JS8DS42SV)
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)
SHEA BUTTER (UNII: K49 155WL9 Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
GRAPE SEED OIL (UNII: 930 MLC8 XGG)
SALICYLIC ACID (UNII: O414PZ4LPZ)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
PEG-60 ALMOND GLYCERIDES (UNII: 4Y0E651N0F)
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)
MASOPROCOL (UNII: 7BO8G1BYQU)
OLEANOLIC ACID (UNII: 6SMK8R7TGJ)
WHITE WAX (UNII: 7G1J5DA97F)
PEG-40 STEARATE (UNII: ECU18C66Q7)
COCOA BUTTER (UNII: 5120 YT1CRR)
LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9 YT4B71U8P)
JOJOBA OIL (UNII: 724GKU717M)
DIMETHICO NE (UNII: 92RU3N3Y1O)
BAMBUSA VULGARIS TOP (UNII: FIW80T6P6V)
OLIVE OIL (UNII: 6UYK2W1W1E)
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)
ROSEMARY (UNII: IJ67X351P9)
AVOCADO OIL (UNII: 6VNO72PFC1)
TRIETHYLENE GLYCOL (UNII: 3P5SU53360)

ı	Pa	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:61402-7131-1	50 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2015	

Labeler - NBC Aesthetics, LLC (078882808)

Revised: 5/2015 NBC Aesthetics, LLC