

H SKIN REPAIR - HYDRATE PLUS RESTORE SUNSCREEN SPF 30- octinoxate and zinc oxide cream

Cosmetic Solutions 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.

H Skin Repair - Hydrate + Restore Sunscreen SPF 30

DRUG FACTS:

ACTIVE INGREDIENTS

Octyl Methoxycinnamate 7.5%

Zinc Oxide 7.0%.

PURPOSE

Sunscreen

USES

Helps prevent sunburn.

WARNINGS

For external use only.

Do not use on damaged or broken skin.

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

Stop use and ask a doctor if rash occurs.

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

DIRECTIONS

Apply to all skin exposed to the sun. *Apply liberally and evenly 15 minutes before sun exposure. *Reapply at least every 2 hours. *Use a water-resistant sunscreen if swimming or sweating. *For children under 6 months of age: Ask a doctor.

Sun Protection Measures.

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this 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 10 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses.

INACTIVE INGREDIENTS

Water (Aqua), Stearyl Alcohol, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Glyceryl Dilaurate, Ceteryl Alcohol, Beeswax, Dimethicone, Cyclomethicone, Diisopropyl Adipate, Hexylene Glycol,

PEG-40 Stearate, C12-15 Alkyl Benzoate, Aluminum Starch Octenylsuccinate, PEG-20, Carnauba Wax, Dimethicone Copolyol, VP/Eicosene Copolymer, Sorbitan Tristearate, Stearoxytrimethylsilane, Steareth-100, Laureth-7, C13-14 Isoparaffin, Phenoxyethanol, Ethylhexylglycerin, Polyacrylamide.

OTHER INFORMATION

Protect the product in this container from excessive heat and direct sun.

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Label

H
skin repair

HYDRATE + RESTORE

sunscreen spf 30+blemish fix
mineral moisture cream

with broad spectrum UVA/UVB
7% zinc oxide, natural beeswax & carnauba

helps reduce the appearance of
redness + repair damaged + dry skin

1 FLUID OUNCE (30mL)



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DRUG FACTS: | **ACTIVE INGREDIENTS:** Octyl Methoxycinnamate 7.5%, Zinc Oxide 7.0%. | **PURPOSE:** Sunscreen. | **USES:** Help prevent sunburn. | **WARNINGS:** For external use only. Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs. Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away. | **DIRECTIONS:** Apply to all skin exposed to the sun. *Apply liberally and evenly 15 minutes before sun exposure. *Reapply at least every 2 hours. *Use a water-resistant sunscreen if swimming or sweating. *For children under 6 months of age: Ask a doctor. **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this 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 10 a.m. - 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses. | **INACTIVE INGREDIENTS:** Deionized Water (Aqua), Stearyl Alcohol, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Glyceryl Dilaurate, Cetearyl Alcohol, Beeswax, Dimethicone, Cyclomethicone, Diisopropyl Adipate, Hexylene Glycol, PEG-40 Stearate, C12-15 Alkyl Benzoate, Aluminum Starch Octenylsuccinate, PEG-20, Carnauba Wax, Dimethicone Copolyol, PVP/Eicosene Copolymer, Sorbitan Tristearate, Stearoxytrimethylsilane, Steareth-100, Laureth-7, C13-14 Isoparaffin, Phenoxyethanol, Ethylhexylglycerin, Polyacrylamide. | **OTHER INFORMATION:** Protect the product in this container from excessive heat and direct sun.

cruelty free
• paraben free •
please recycle
MANUFACTURED for
H SKIN REPAIR
Naples, Florida 34103
www.hskinrepair.com

H SKIN REPAIR - HYDRATE PLUS RESTORE SUNSCREEN SPF 30

octinoxate and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66 163-6404
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	75 mg in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	70 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Stearyl Alcohol (UNII: 2KR89I4HIY)	
Glycerin (UNII: PDC6A3C0OX)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
PEG-100 Stearate (UNII: YD01N1999R)	
Glyceryl Dilaurate (UNII: MFL3ZIE8SK)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Dimethicone (UNII: 92RU3N3Y1O)	
Cyclomethicone (UNII: NMQ347994Z)	
Diisopropyl Adipate (UNII: P7E6YFV72X)	
Hexylene Glycol (UNII: KEH0A3F75J)	
PEG-40 Stearate (UNII: ECU18C66Q7)	
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Aluminum Starch Octenylsuccinate (UNII: I9PJ0O6294)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
Carnauba Wax (UNII: R12CBM0EIZ)	
PEG/PPG-18/18 Dimethicone (UNII: 9H0AO7T794)	
Sorbitan Tristearate (UNII: 6LUM696811)	
Stearoxytrimethylsilane (UNII: 9862TW94B2)	
Steareth-100 (UNII: 4OH5W9UM87)	
Laureth-7 (UNII: Z95S6G8201)	
C13-14 Isoparaffin (UNII: E4F12ROE70)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Ethylhexylglycerin (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66163-6404-1	30 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/01/2019	

Labeler - Cosmetic Solutions LLC (807907928)