SPF 30 MINERAL SUNSCREEN FACE NECK- zinc oxide cream
Allure Labs 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.

DRUG FACTS

Active Ingredients: Zinc Oxide - 18.6%

Purpose: Sunscreen

Uses:

- High protection against sunburn.
- Higher SPF gives more sunburn protection.
- 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 10am - 2pm.
- Wear long sleeved shirts, pants, hats and sunglasses.

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 occurs. Do not use on damaged or broken skin.

Keep out of reach of children

Directions:

- Apply generously 15 minutes before su exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply as needed or after towel drying, swimming or perspiring.
- Children under 6 months of age: ask a doctor.

Other Information

- Sun Alert: limiting sun exposure, wearing protective clothing and using sunscreen may reduce the risk of skin aging, skin cancer and other harmful effects of the sun.

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

Water (Aqua), Cyclopentasiloxane, Butylene Glycol, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Cyclohexasiloxane, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Sorbitan Stearate, Dimethicone, Cetyl Alcohol, Caprylic/Capric Triglyceride, Organic Butyrospermum Parkii (Shea) Butter, Polyacrylamide, C13-14 Isoparaffin, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Sodium Hyaluronate, Dipotassium Glycyrrhizate, Tocopheryl Linoleate/Oleate, Physalis Angulata Extract, Teprenone, Leontopodium Alpinum Meristem Cell Culture, Polygonum Aviculare Extract, Imperata Cylindrica Root Extract, Arabidopsis Thaliana Extract, Plankton Extract, Micrococcus Lysate, Organic Camellia Sinensis Leaf Extract, Phoenix Dactylifera (Date) Fruit Extract, Sidium Lactete, Palmitoyl Tripeptide-1, Palmitoyl Tetrapeptide-7, Organic Aloe Barbadensis Leaf Juice, Lecithin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate-20, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Laureth-7, Xanthan Gum, Carbomer, PEG-8, Tocopherol, Ascorbyl Palmitate, Ascorbic Acid, Citric Acid, Disodium EDTA.

Made in USA

Distributed by OJAS, LLC

OjasSkin.com

SPF 30 MINERAL SUNSCREEN FACE NECK

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62742-4086
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	186 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
PHYSALIS ANGULATA (UNII: W4TKW9D5GG)	
TEPRENONE (UNII: S8S8451A4O)	
LEONTOPODIUM ALPINUM FLOWERING TOP (UNII: QQC1AK06RK)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
IMPERATA CYLINDRICA ROOT (UNII: VYT2JA85NH)	
ARABIDOPSIS THALIANA (UNII: AI3L60HQ81)	
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)	
PHOENIX RECLINATA FRUIT (UNII: B140O227ZE)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
LAURETH-7 (UNII: Z95S6G8201)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4086-1	2 mL in 1 TUBE; Type 0: Not a Combination Product	07/14/2016	
2	NDC:62742-4086-3	1 in 1 CARTON	07/14/2016	
2	NDC:62742-4086-2	50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/11/2016	

Labeler - Allure Labs Inc (926831603)

Establishment

Name	Address	ID/FEI	Business Operations
Allure Labs Inc		926831603	manufacture(62742-4086)

Revised: 7/2016 Allure Labs Inc