

SHEER PROTECTION SPF 30- zinc oxide cream

Skin Script, 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.

Active Ingredient(s): Zinc Oxide (13.5%)

Purpose: Sunscreen

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

Uses:

- Helps prevent sunburn
- If used as directed with other 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 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 the product is swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- Apply liberally 15 min before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours
- Children under 6 months: 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 of 15 or higher and other sun protection measures including: Limit time in the sun, especially from 10am - 2pm. Wear long sleeve shirts, pants, hats, and sunglasses.

Inactive Ingredients: Aqua (Water), Caprylic/Capric Triglyceride, Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters, Glycerin, Isodecyl Neopentanoate, Ethyl Macadamiate, Aleurites Moluccanus Seed Oil, Hydroxypropyl Starch Phosphate, Glyceryl Stearate, Hamamelis Virginiana (Witch Hazel) Water, Ergothioneine (L), Hordeum Distichon (Barley) Extract, Macadamia Ternifolia Seed Oil, Porphyra Umbilicalis (Red Algae) Extract, Santalum Album (Sandalwood) Extract, Phellodendron Amurense Bark Extract, Bisabolol (L-alpha), Glyceryl Isostearate, Sodium Stearoyl Lactylate, Polyglyceryl-10 Pentastearate, Polyhydroxystearic Acid, Tocopheryl Acetate (D-alpha), Tocopherol (D-alpha), Lecithin, Malic Acid (L), Lonicera Caprifolium (Honeysuckle) Flower Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Potassium Cetyl Phosphate, Hydrogenated Palm Glycerides, Alcohol, Cetearyl Alcohol, Behenyl Alcohol, Hydroxypropyl Methylcellulose, Sodium Lactate, Phytic Acid, Citric Acid, Sodium Hydroxide

Other Information:

- Protect the product from excessive heat and direct sun.

Tone Indicates Non-Print Areas

SKIN SCRIPT™

Sheer Protection SPF 30

with 13.5% Zinc Oxide
UVA/UVB Broad Spectrum Coverage

Light, Comfortable Sun Protection

YOUR PRESCRIPTION FOR SKIN CARE

2 oz (60 gms)

DRUG FACTS:

Active Ingredient(s): Zinc Oxide (13.5%)	Purpose: Sunscreen
Uses: <ul style="list-style-type: none">Helps prevent sunburnIf used as directed with other protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun.	
Warnings: <ul style="list-style-type: none">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 the product is swallowed, get medical help or contact a Poison Control Center right away.	
Directions: <ul style="list-style-type: none">Apply liberally 15 min before sun exposure.Use a water resistant sunscreen if swimming or sweating.Reapply at least every 2 hours.Children under 6 months: 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 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 sleeve shirts, pants, hats and sunglasses.	
Inactive Ingredients: Aqua (Water), Caprylic/Capric Triglyceride, Candelilla, Jojoba/Rice Bran Polyglyceryl-3 Esters, Glycerin, Isodecyl Neopentanoate, Ethyl Macadamate, Aleurites Moluccanus Seed Oil, Hydroxypropyl Starch Phosphate, Glyceryl Stearate, Hamamelis Virginiana (Witch Hazel) Water, Ergothioneine (L), Hordeum Distichon (Barley) Extract, Macadamia Ternifolia Seed Oil, Porphyra Umbilicalis (Red Algae) Extract, Santalum Album (Sandalwood) Extract, Phellodendron Amurense Bark Extract, Bidbalol (L-alpha), Glyceryl Isostearate, Sodium Stearoyl Lactylate, Polyglyceryl-10 Pentastearate, Polyhydric Stearic Acid, Tocopheryl Acetate (D-alpha), Tocopherol (D-alpha), Lecithin, Malic Acid (L), Lonicera Caprifolium (Honeysuckle) Flower Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Potassium Cetyl Phosphate, Hydrogenated Palm Glycides, Alcohol, Cetearyl Alcohol, Behenyl Alcohol, Hydroxypropyl Methylcellulose, Sodium Lactate, Phytic Acid, Citric Acid, Sodium Hydroxide	
Other Information: <ul style="list-style-type: none">Protect this product from excessive heat and direct sun.	
Distributed by: Skin Script™ Tempe, AZ 85283	

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SHEER PROTECTION SPF 30

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83657-610
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0135 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)	
PEG-60 GLYCERYL STEARATE (UNII: 85O35YN6YY)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
PHELLODENDRON AMURENSE BARK (UNII: PBG27B754G)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WITCH HAZEL (UNII: 101I4J0U34)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
ALCOHOL (UNII: 3K9958V90M)	
DOCOSANOL (UNII: 9G1OE216XY)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
LEVOMENOL (UNII: 24WE03BX2T)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
SANDALWOOD (UNII: 3641YW25N2)	
LONICERA CAPRIFOLIUM FLOWER (UNII: 5N1WD9784U)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WATER (UNII: 059QF0KO0R)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
BARLEY (UNII: 5PWW7YLI7R)	
HYDROXYPROPYL CORN STARCH (5% SUBSTITUTION BY WEIGHT) (UNII: 9M44R3409A)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
ALEURITES MOLUCCANA SEED (UNII: J87WJ3E7VW)	
POLYGLYCERYL-10 STEARATE (UNII: 90TF85HH91)	
MALIC ACID, L- (UNII: J3TZF807X5)	
MACADAMIA OIL (UNII: 515610SU8C)	
ERGOTHIONEINE (UNII: BDZ3DQM98W)	
FYTIC ACID (UNII: 7IGF0S7R8I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83657-610-03	60 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2012	
2	NDC:83657-610-08	7.5 g in 1 JAR; Type 0: Not a Combination Product	01/01/2012	
3	NDC:83657-610-63	7 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	01/01/2012	

Labeler - Skin Script, LLC (050951910)

Revised: 9/2023

Skin Script, LLC