

SHUNLY ZN20 LIGHT MOISTURIZER- zinc oxide cream
Shunly Skin Care LLC

DRUG FACTS

ACTIVE INGREDIENTS:

Zinc Oxide 20%

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 aging caused by the sun.

WARNINGS:

For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

DIRECTIONS:

- Apply liberally 15 minutes before sun exposure
- Reapply:
- After 40 minutes of swimming or sweating
 - Immediately after towel drying
 - 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 value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 am- 2 pm
 - Wear long sleeve shirts and hats and sunglasses

INACTIVE INGREDIENTS:

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone

Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxytearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun
- May stain some fabrics.

FREE FROM: Chemical Sunscreens, Oils, PABA, Parabens, Fragrances

Manufactured for: Shunly Skin Care LLC Meridian, ID 83646

www.shunlyskincare.com

Principal Display Panel - 113 g Bottle Label

shunly®

A BOTTLE
FULL OF SKINCARE

Zn20+

**SPF40 Light
Moisturizer**

Broad Spectrum UV Defense

**FUSION FORMULA® with
Zinc Oxide 20% / C / E**

Water Resistant (40 mins)

NET.WT. 4 oz 113 g

DRUG FACTS (cont)

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3 SkinCareACTS™ Protection

shunly®
A BOTTLE
FULL OF SKINCARE

Zn20+ SPF40 Light Moisturizer

.....
Broad Spectrum UV Defense
.....

**FUSION FORMULA® with
Zinc Oxide 20% / C / E**

Water Resistant (40 mins)

NET.WT. 4 oz | 113 g

Broad spectrum UVA1 / UVA / UVB daily moisturizer offering high SPF protection from photo-aging. Apply evenly on skin before sun exposure and re-apply if active, sweaty, or after swimming.

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SHUNLY ZN20 LIGHT MOISTURIZER

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81381-205
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
DIMETHICONE 100 (UNII: RO266O364U)
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)
EDETATE DISODIUM (UNII: 7FLD91C86K)
GLYCERIN (UNII: PDC6A3C0OX)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z591F64N)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
TROLAMINE (UNII: 9O3K93S3TK)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81381-205-04	113 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/01/2022	

Labeler - Shunly Skin Care LLC (040374013)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(81381-205)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(81381-205) , PACK(81381-205)

