

KORU PERFORMANCE SUNSCREEN SPF40- sunscreen lotion
Koru Performance 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.

Koru Performance Sunscreen Lotion SPF 40

Active Ingredient

Zinc Oxide 20%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- Provides high protection against sunburn.
- Retains SPF after 80 minutes of swimming or sweating.

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 or irritation develops and lasts

Keep out of reach of children

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure

- Use a water-resistant sunscreen if swimming or sweating.
- Reapply

Immediately after towel drying
At least every 2 hours

- 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 am to 2 pm
 - wear long-sleeved shirts, pants, hats and sunglasses

Other Information

Protect this product from excessive heat and direct sun.

Inactive Ingredients

Batitol, Butylene glycol, Ceresin, Cetyl alcohol, Cocoyl caprylocaprate, Dimethicone, Disteardimonium hectorite, Edetate disodium, Ethylhexylglycerin, Ethyl ferulate, Medium chain triglycerides, Neopentyl glycol dicaprate, Pentaerythrityl tetraethylhexanoate, Phenoxyethanol, Polyglyceryl-3 pentaricinoleate, Polyglyceryl-4 isostearate, Propanediol, Propanediol dicaprylate, Silicon dioxide, Sorbitan isostearate, Styrene/Acrylamide copolymer (MW 500000), Triethoxycaprylsilane, Water

Bottle Label



KORU PERFORMANCE SUNSCREEN SPF40
sunscreen lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81129-001
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 mL

Inactive Ingredients

Ingredient Name	Strength
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
PROPANEDIOL DICAPRYLATE (UNII: C5770MC6UH)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BATILOL (UNII: 39YR661C4U)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)	
ETHYL FERULATE (UNII: 5B8915UELW)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
CERESIN (UNII: Q1LS2UJO3A)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPANEDIOL (UNII: 5965N8W85T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PENTAERYTHRITYL TETRAETHYLHEXANOATE (UNII: XJ7052W897)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81129-001-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part352	08/01/2021	
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Labeler - Koru Performance LLC (117749158)

Establishment

Name	Address	ID/FEI	Business Operations
TAKA USA Inc. dba Cosmetic Innovations		802860515	manufacture(81129-001)

Revised: 7/2021

Koru Performance LLC