

THE DAY FORMULA BROAD SPECTRUM SPF 30 SUNSCREEN- titanium dioxide cream
Dar Companies, 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.

The Day Formula

DRUG FACTS

Active Ingredient

Titanium Dioxide 8.8%

Purpose

Sunscreen

Use

- Helps prevent sunburn
- If used as directed with other sun protection measures, decreases the risk of skin cancer and early signs of 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 product is swallowed, get medical help or call a Poison Control Center immediately

Directions

- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours
- Use water resistant sunscreen if swimming or sweating.
- Sun Protection Measures Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the 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.

- Children under 6, ask a doctor.

Other Information

Protect this product from excessive heat and direct sun.

Inactive Ingredients

Water, C12-15 Alkyl Benzoate, Propanediol, Benzotriazolyl Dodecyl p-Cresol, Butylene Glycol, Butyloctyl Salicylate, Niacinamide, Polymethylsilsesquioxane, Silica, Aluminum Stearate, Polyhydroxystearic Acid, 1,2-Hexanediol, Pentylene Glycol, Caprylic/Capric Triglyceride, Alumina, Ammonium Acryloyldimethyltaurate/VP Copolymer, Polyacrylate Crosspolymer-6, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Sodium Stearoyl Glutamate, Octyldodecanol, Polyisobutene, Hydroxypropyl Methylcellulose Stearoxy Ether, Stearic Acid, Ethylhexylglycerin, Xanthan Gum, Echium Plantagineum Seed Oil, Sorbitan Oleate, Caprylic/Capryl Glucoside, t-Butyl Alcohol, Cardiospermum Halicacabum Flower/Leaf/Vine Extract, Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables, Tocopherol

Dist. by DAR Companies
New York, NY 10001
and Dublin, Ireland

PRINCIPAL DISPLAY PANEL - 35 ML Bottle Carton

DR.
ROSSI
DERM MD
CLEAN, CLINICAL SCIENCE™

THE DAY FORMULA
BROAD SPECTRUM
SPF 30 SUNSCREEN
PA +++
PROTECTION SOLAIRE
LARGE SPECTRUM

Active Ingredient: Titanium Dioxide 8.8%
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Dist. by DAR Companies
New York, NY 10001
and Dublin, Ireland
rossidermmd.com

Made in Korea/Fabriqué en Corée

35ML / 1.2 FL. OZ.



DRUG FACTS cont'd

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THE DAY FORMULA
BROAD SPECTRUM
SPF 30 SUNSCREEN
PA +++
PROTECTION SOLAIRE
LARGE SPECTRUM

0.583

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1 5/8

29/32

KNOCKOUT FOR GLUEING

UPC
GOES HERE
850025044042

500006



THE DAY FORMULA BROAD SPECTRUM SPF 30 SUNSCREEN

titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80518-123
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	88 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
Propanediol (UNII: 5965N8W85T)	
BENZOTRIAZOLYL DODECYL P-CRESOL (UNII: 298PX4M11X)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
NIACINAMIDE (UNII: 25X51I8RD4)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ECHIUM PLANTAGINEUM SEED OIL (UNII: PIB7XBU8XW)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
CARDIOSPERMUM HALICACABUM FLOWERING TOP (UNII: MZP2508BRR)	

SUNFLOWER OIL UNSAPONIFIABLES (UNII: T7ZE2WA4MB)	
TOCOPHEROL (UNII: R0ZB2556P8)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80518-123-01	1 in 1 CARTON	09/01/2022	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2022	

Labeler - Dar Companies, LLC (117641085)

Revised: 5/2023

Dar Companies, LLC