

DOCTOR BABOR PROTECT RX MINERAL SUNSCREEN SPF 30- zinc oxide cream
BABOR Cosmetics America Corp

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.

Doctor Babor Protect Rx Mineral Sunscreen SPF 30

Drug Facts

Active Ingredient

Zinc Oxide 18.22%

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.

When using the 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 contact a Poison Control Center right away.

Directions

- reapply generously 15 minutes before sun exposure as needed.
- reapply at least every 2 hours

- use a water-resistant sunscreen if swimming or sweating
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early 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
- children under 6 months: Ask a doctor.

Inactive Ingredients

water/aqua/eau, caprylic/capric triglyceride, C13-15 Alkane, pentylene glycol, C15-19 Alkane, propanediol, bis-diglyceryl polyacyladipate-2, gluconolactone, polyhydroxystearic acid, polyacrylate crosspolymer-6, cetearyl alcohol, inositol, isostearic acid, lecithin, polyglyceryl-3 lactate/laurate, sodium benzoate, tocopherol, bisabolol, xanthan gum, behenyl alcohol, sodium citrate, sodium dilaureamidoglutamide lysine, sclerotium gum, arachidyl glucoside, citric acid, physalis alkakengi calyx extract, sodium phytate, t-butyl alcohol, calcium gluconate, glucose, beta-carotene.

Other Information

- protect this product from excessive heat and direct sun

Questions or comments?

You may report serious adverse event from the use of this product.

Call toll free 1-800-333-4055

Company Information

Made in the USA

Manufactured for:

BABOR Cosmetics America Corp.

2980 NE 207th St, Ste 402 Aventura,

FL 33180 www.babor.com

Product Packaging

DOCTOR
BABOR

PROTECT
RX



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REEF SAFE

A clean, lightweight, non-nano mineral sunscreen that provides UVA/UVB protection while also moisturizing the skin without a greasy residue. Suitable for all skin types. Reef safe.

- **Zinc Oxide 18.22%:** Mineral UV filter
- **Inositol:** An osmolyte that helps to protect skin from environmental stress like oxidative (UV radiations) and thermal stress (dehydration) by protecting the moisture barrier.
- **Bisabolol:** Helps to calm the skin.

- **Physalis Alkekengi Calyx Extract (and Beta-Carotene):** Helps to protect the skin from environmental aggressors.
- **Tocopherol:** Antioxidant, moisturizing
- **Pentylene Glycol:** Active performance booster, moisturizer, sustainable ingredient
- **Propanediol:** Enhances moisturization, boost preservation, skin-friendly

Sonnenschutzmittel SPF 30 • Sunscreen SPF 30 • Produit de protection solaire FPS 30 • Zonnebrand SPF 30 • Protector solar SPF 30 • Protezione solare SPF 30 • Solkrem SPF 30 • Солнцезащитное средство SPF 30 • Solbeskyttelsesmiddel SPF 30 • Auringonsuoja-aine SPF 30 • Solskyddsmedel SPF 30 • Preparat chroniacy przed słońcem z filtrem SPF 30 • Sluneční ochrana SPF 30 • Zaščitno sredstvo za sončenje SPF 30 • Fényvédőszer SPF 30 • Protetor solar SPF 30 • Güneşten koruyucu ürün SPF 30 • Αντηλιακό SPF 30 • Pálkesekaltsevahend SPF 30 • Saulės aizsarglīdzeklis SPF 30 • Apsaugos nuo saulės priemonė SPF 30 • sredstvo za zaštitu od sunca SPF 30 • Produs de protecție solară SPF 30 • Zaščitno sredstvo za sončenje SPF 30 • Солнцезащитное средство SPF 30 • 防曬霜 SPF 30

MINERAL
SUNSCREEN SPF 30

BROAD SPECTRUM
SPF 30

CRÈME SOLAIRE
MINÉRALE FPS 30

30

- Provides broad-spectrum UVA/UVB sun protection
- Smooth finish
- No white residue

Net 1 fl. oz. (30 ml)

Drug Facts (continued)

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Ref. 4.013.66

DOCTOR BABOR PROTECT RX MINERAL SUNSCREEN SPF 30

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44924-901
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	182.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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INOSITOL (UNII: 4L6452S749)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
CALCIUM GLUCONATE (UNII: SQE6VB453K)	
BETA CAROTENE (UNII: 01YAE03M7J)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PROPANEDIOL (UNII: 5965N8W85T)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
C15-19 ALKANE (UNII: CI87N1IM01)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
AMMONIUM ACRYLOYLDIMETHYLAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
COCO GLUCOSIDE (UNII: ICS790225B)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
XANTHAN GUM (UNII: TTV12P4NEE)	
DOCOSANOL (UNII: 9G1OE216XY)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
PHYSALIS ALKEKENGII CALYX (UNII: AL7F9NO9HR)	
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	
SODIUM DILAURAMIDOGlutAMIDE LYSINE (UNII: MNJ7VPT2R5)	
BIS-DIGLYCERYL POLYACYLADIPATE-2 (UNII: 6L246LAM9T)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
C13-15 ALKANE (UNII: 114P5I43UJ)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
LEVOMENOL (UNII: 24WE03BX2T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44924-901-01	1 in 1 CARTON	02/01/2022	
1		30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph			

OTC monograph not final	part352	02/01/2022	
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Labeler - BABOR Cosmetics America Corp (139251763)

Revised: 11/2021

BABOR Cosmetics America Corp