

SUNSCREEN - spf 40 lotion
CA-BOTANA INTERNATIONAL

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.

6236 SPF40 Umbrella Sunscreen Lotion

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 contact a poison control center right away.

Helps prevent sunburn. If used as directed with other sun protection measured decreases the risk of skin cancer and early skin aging caused by the sun. Apply liberally 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply: at least 2 hours. Children under 6 months: Ask a doctor. Sun protection measurements. 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. Protect this product from excessive heat and direct sun

ALOE VERA LEAF, ALUMINUM STARCH OCTENYLSUCCINATE, ASCORBIC ACID, ASCORBYL PALMITATE, BORON NITRIDE, CETOSTEARYL ALCOHOL, CETEARYL ISONONANOATE, CITRIC ACID MONOHYDRATE, CAPRYLIC/CAPRIC MONO/DIGLYCERIDES, ETHYLHEXYLGLYCERIN, GLYCERIN, SUNFLOWER OIL, ISOMALT, LECITHIN SOYBEAN, MACADAMIA OIL, NIACIN, PANTHENOL, PHENOXYETHANOL, LECITHIN SOYBEAN, POTASSIUM SORBATE, PROPANEDIOL, ROSA MOSCHATA OIL, ROSEMARY, SODIUM BENZOATE, HYALURONATE SODIUM, TETRASODIUM IMINODISUCCINATE, TOCOPHEROL, GRAPE SEED OIL, WATER

Sunscreen

Titanium Dioxide, Octinoxate

For external use only.

Avoid contact with eyes.

Keep out of reach of children.

Do not apply to open wounds.

STOP USE AND ask a doctor if condition worsens or symptoms persist for more than seven days, discontinue use of the product.

Helps prevent sunburn. If used as directed with other sun protection measured decreases the risk of skin cancer and early skin aging caused by the sun. Apply liberally 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply: at least 2 hours. Children under 6 months: Ask a doctor. Sun protection measurements. 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. Protect this product from excessive heat and direct sun



DOCTOR D.
SCHWAB®
UMBRELLA SUNSCREEN

BROAD SPECTRUM
SPF 40

ENVIRONMENTAL PROTECTION
CRÈME SOLAIRE HYDRATANTE
HUMECTANTE PROTECCIÓN SOLAR



4 oz. / 113.4 g

Drug Facts

Active Ingredients Titanium Dioxide 6%..... Sunscreen
Octinoxate 7.5%..... Sunscreen

Uses • helps prevent sunburn • If used as directed with other sun protection measured (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 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 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: Aloe Barbadosis Extract, Aluminum Starch Octenylsuccinate, Ascorbic Acid, Ascorbyl Palmitate, Boron Nitride, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Cetearyl Isononanoate, Citric Acid, Coco Caprylate, Emulsifying wax, Ethylhexylglycerin, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Isomalt, Lecithin, Macadonia Ternifolia Seed Oil, Niacin, Panthenol, Phenylethanol, Phospholipids, Potassium Sorbate, Propandiol (Zemeol), Rosa Canina Fruit (Rosehip) Oil, Rosmarinus Officinalis Leaf (Rosemary) Extract CO2, Sodium Benzoate, Sodium Hyaluronate, Tetrasodium EDTA, Tocopherol, Vitis Vinifera (Grape) Seed Extract Water (Aqua)

Other information • protect this product from excessive heat and direct sun.

NDC #: 35192-008-02

REF #6236



DOCTOR D. SCHWAB®

Manufactured by CA BOTANICA

San Diego, CA 92121, USA

Made in USA

www.DoctorSchwabCA.com

Enter section text here

SUNSCREEN

spf 40 lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35192-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	6.8 g in 113.4 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	8.5 g in 113.4 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL ISONONANOATE (UNII: P5O01U99N1)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795Y1)	
ISOMALT (UNII: S870P55O2W)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MACADAMIA OIL (UNII: 515610SU8C)	
NIACIN (UNII: 2679MF687A)	
PANTHENOL (UNII: WV9CM0O67Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPANEDIOL (UNII: 5965N8W85T)	
ROSA MOSCHATA OIL (UNII: J99W255AWF)	
ROSEMARY (UNII: IJ67X351P9)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TETRASODIUM IMINODISUCCINATE (UNII: GYS41J2635)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:35192-008-02	113.4 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	06/01/2012		

Labeler - CA-BOTANA INTERNATIONAL (106276728)

Registrant - RODOLFO UGELSTAD (106276728)

Establishment			
Name	Address	ID/FEI	Business Operations
CA-BOTANA INTERNATIONAL		106276728	manufacture

Revised: 6/2012

CA-BOTANA INTERNATIONAL