

SPF 50 DAILY UV DEFENSE BROAD SPECTRUM SUNSCREEN- octinoxate, zinc oxide cream

Vi Medical Products, INC

SPF 50 Daily UV Defense Broad Spectrum Sunscreen

Active ingredients purpose

Octinoxate 7.5% Sunscreen

Zinc Oxide 10.8 Sunscreen

Uses: Helps prevent sunburn if used as directed with other sun protection (**see directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

Keep out of reach of children. If swallowed, get help or contact a Poison Control Center right away.

Stop use and ask a doctor if rash occurs

Warnings:

For external use only. Avoid contact with eyes. Rinse with water to remove. Do not use on damaged or broken skin.

Directions: Apply liberally and evenly 15 minutes before sun exposure. Reapply as needed or after towel drying, swimming, or sweating.

Sun Protection Measures: Spending time in the sun increases 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 10am-2pm. Wear long-sleeved shirts, pants, hats and sunglasses

Reapply at least 2 hours. Use a water resistant sunscreen if swimming or sweating.

Children under 6 months, ask a doctor.

Inactive ingredients: Water, Polysorbate 60, Coconut Alkanes, C12-15 Alkyl Benzoate, Octyldodecanol Neopentanoate, Glycerin, Cetearyl Alcohol, Cyclopentasiloxane, Glyceryl Stearate, PEG-100 Stearate, Benzyl Alcohol, Dimeticone, Xanthan Gum, Phenoxyethanol, Ethylhexylglycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Disodium EDTA, Camellia Sinensis Leaf Extract, Aloe Barbadensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Citrus Limon (Lemon) Fruit Extract, Pueraria Lobata Root Extract

Vitality Institute

SPF 50 Daily UV Defense Broad Spectrum Sunscreen

2 Fl Oz / 59 mL

PANTONE 5473 CP

SILVER FOIL HOT STAMP: 2 panels (GWF #110 SILVER) on logo and the words For Confident skin



VI DERM
WHITE



24 PT.SBS

PRINT 1 COLOR 5437C WITH SOFT TOUCH,
PLUS BLACK FOR UPC

WITH SOFT TOUCH AND SILVER FOIL STAMP
ON 2 PANELS (GWF #110 SILVER) ON THE
LOGO AND THE WORDS "for confident skin"

SPF 50 DAILY UV DEFENSE BROAD SPECTRUM SUNSCREEN

octinoxate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70484-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10.8 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PUERARIA MONTANA VAR. LOBATA ROOT (UNII: PET93F4I3C)	
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S) (UNII: 8Z5ZAL5H3V)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	
MATRICARIA RECUTITA FLOWERING TOP (UNII: 3VNC7T6Z02)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
LEMON (UNII: 24RS0A988O)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0KO0R)	
COCONUT ALKANES (UNII: 1E5KJY107T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70484-008-02	1 in 1 CARTON	02/06/2025	
1	NDC:70484-008-01	59 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70484-008-04	1 in 1 CARTON	02/06/2025	
2	NDC:70484-008-03	30 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/06/2025	

Labeler - Vi Medical Products, INC (063910521)

