# SUNSCREEN BROAD SPECTRUM SPF 50 VI AESTHETICS- zinc oxide, octinoxate cream Vi Medical Products, INC

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.

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### Vitality Institute Skin Care System SPF 50+

Active Ingi	Purpose	
Octinoxate	7.5%	Sunscreen
Zinc Oxide	10%	. Sunscreen

### Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (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
- When using this product keep out of eyes. Rinse with water to remove

### Directions

- [Apply evenly 15 minutes before sun exposure
- Reapply at least every 2 hours 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 the risk, regularlyy use a sun screen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including
- Sun protection Measures: Spending time in the sun increases risk of skin cancer and early skin aging. To decrease the risk, regularlyy use a sun screen 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 months of age: Aski a doctor

### **Inactive Ingredients**

Water, C12-15, Alkyl Benzoate, Octyldodecly Neopentanoate, Polysorbate 60, Cetearyl Alcohol, Glycerin, Cyclopentasiloxane, Glyceryl Stearate, PEG - 100 Stearate, Coconut Alkanes, Polyhydroxystearic Acid, Coco-Caprylate/Caprate, Dimethicone, Aloe Barbadensis Leaf Extract, Citrus Grandis Fruit Extract, Anthemis Nobilis Flower Extract, Pueraria Lobata Root Extract, Camellia Sinensis Leaf Extract, Disodium EDTA, Xanthan Gum, Acrylates/C10-30 Alkyl Acrylates Crosspolymer, Benzyl Alcohol, Ehtylhexylglycerin, Phenoxyethanol

VI Derm

SPF 50+ Cream

Sunscreen Broad Spectrum



SPF 50+ CREAM

SUNSCREEN **BROAD SPECTRUM** 



Active Ingredients: Octinoxate 7.5% Zinc Oxide 10%

59 mL/2 FL OZ



### **Drug Facts**

ACTIVE INGREDIENTS	<b>PURPOSE</b>
Octinoxate 7.5%	
Zinc Oxide 10%	Sunscreen

**USES** • Helps prevent sunburn • If used as directed with other Sun Protection Measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

WARNINGS • For External use only • Avoid contact with eyes. Rinse with water to remove • Stop use and ask a doctor if rash occurs • Keep out of reach of children. If swallowed, get help or contact a Poison Control Center right away.

**DIRECTIONS** • Apply 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 broad spectrum SPF of 15 or higher and other sun protection measures including: • limit time in the sun, especially from 10 am - 2 pm • wear long-sleeve shirts, pants, hats, and sunglasses • Reapply at least every 2 hours • Use a water resistant sunscreen if swimming or sweating • Children under 6 months: Ask a doctor

#### **INACTIVE INGREDIENTS**

Water, C12-15 Alkyl Benzoate, Octyldodecyl Neopentanoate, Polysorbate 60, Cetearyl Alcohol, Glycerin, Cyclopentasiloxane, Glyceryl Stearate, PEG-100 Stearate, Coconut Alkanes, Polyhydroxystearic Acid, Coco-Caprylate/Caprate, Dimethicone, Aloe Barbadensis Leaf Extract, Citrus Grandis Fruit Extract, Anthemis Nobilis Flower Extract, Pueraria Lobata Root Extract, Camellia Sinensis Leaf Extract, Disodium EDTA, Xanthan Gum, Acrylates/C10-30 Alkyl Acrylates Crosspolymer, Benzyl Alcohol, Ethylloxylalycerin, Phenoxyethanol Alcóhol, Ethylhexylglycérin, Phénoxyethanol

OTHER INFORMATION • Protect from excessive heat and direct sunlight.



Distributed by: VI Aesthetics Made in the USA Los Angeles, CA 90230 | 855.VI.PEELS | www.vipeel.com



### SUNSCREEN BROAD SPECTRUM SPF 50 VI AESTHETICS

zinc oxide, octinoxate cream

**Product Information** 

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70484-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	10 g in 100 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
OCTYLDO DECYL NEO PENTANO ATE (UNII: X8725R883T)			
POLYSORBATE 60 (UNII: CAL22UVI4M)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
Glycerin (UNII: PDC6A3C0OX)			
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0R)			
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)			
PEG-100 STEARATE (UNII: YD01N1999R)			
COCONUT ALKANES (UNII: 1E5KJY107T)			
POLYHYDRO XYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)			
COCO-CAPRYLATE/CAPRATE (UNII: 8 D9 H4QU99 H)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			
ALOE VERA LEAF (UNII: ZY81Z83H0 X)			
PUMMELO (UNII: ET1TN5W71X)			
CHAMAEMELUM NO BILE FLO WER (UNII: O2T154T6OG)			
PUERARIA MONTANA VAR. LOBATA ROOT (UNII: PET93F4I3C)			
GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)			
XANTHAN GUM (UNII: TTV12P4NEE)			
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)			
BENZYL ALCOHOL (UNII: LKG8494WBH)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
PHENO XYETHANOL (UNII: HIE492ZZ3T)			

P	Packaging				
#	# Item Code Package Description		<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:70484-005-02	1 in 1 BOX	03/26/2015		
1	NDC:70484-005-01	30 mL in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:70484-005-04	1 in 1 BOX	03/26/2015		
2	NDC:70484-005-03	59 mL in 1 TUBE; Type 0: Not a Combination Product			

<b>Marketing Infor</b>	mation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part352	03/26/2015

## Labeler - Vi Medical Products, INC (063910521)

## Registrant - VEGE-KURL, INC (021072509)

Establishment			
Name	Address	ID/FEI	Business Operations
VEGE-KURL, INC		021072509	manufacture (70484-005)

Revised: 3/2017 Vi Medical Products, INC