

SUNSCREEN BROAD SPECTRUM SPF 50 VITALITY INSTITUTE- zinc oxide, octinoxate cream

Vitality Institute Medical Products

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.

Vitality Institute Skin Care System SPF 50+

Active Ingredients Purpose

Zinc Oxide 10% Sunscreen

Octinoxate 7.5% 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, regularly 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, regularly 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: Ask a doctor

Inactive Ingredients

Water, C12-15, Alkyl Benzoate, Octyldodecyl Neopentanoate, Polysorbate 60, Cetaryl Alcohol, Glycerin, Cyclopentasiloxane, Glyceryl Stearate, PEG - 100 Stearate, Coconut Alkanes, Polyhydroxystearic Acid, Coco-Caprylate/Caprates, Dimethicone, Aloe Barbadosis 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, Ethylhexylglycerin, Phenoxyethanol

Vitality Institute Skin Care System

SPF 50+



SPF 50+
CREAM

SUNSCREEN
BROAD SPECTRUM



Active Ingredients:
Octinoxate 7.5%
Zinc Oxide 10%

30 mL/1 FL OZ

Drug Facts

ACTIVE INGREDIENTS	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.

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, Ethylhexylglycerin, Phenoxyethanol

OTHER INFORMATION • Protect from excessive heat and direct sunlight.

Sample Size Not For Resale
Distributed by: **Vitality Institute Medical Products**
Culver City, CA 90230 | 855.VI.PEELS www.vipeel.com



SUNSCREEN BROAD SPECTRUM SPF 50 VITALITY INSTITUTE

zinc oxide, octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69718-155
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 17.5 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 17.5 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
Glycerin (UNII: PDC6A3C0OX)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PUMMELO (UNII: ET1TN5W71X)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
PUERARIA MONTANA VAR. LOBATA ROOT (UNII: PET93F4I3C)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69718-155-02	1 in 1 BOX		
1	NDC:69718-155-01	30 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69718-155-04	1 in 1 BOX		
2	NDC:69718-155-03	59 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 final	part352	03/26/2015	

Labeler - Vitality Institute Medical Products (056496844)

Registrant - VEGE-KURL, INC (021072509)

Establishment

Name	Address	ID/FEI	Business Operations
VEGE-KURL, INC		021072509	manufacture(69718-155)

