

CHEM-FREE ACTIVE DEFENSE SPF 30- zinc oxide cream

Van Laere LLC

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.

Chem-Free Active Defense SPF 30

Drug Facts

Active Ingredient

Zinc Oxide 17.5%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- Retains SPF after 80 minutes of activity in the water or perspiring

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 swallowed, get medical help or contact a Poison Control Centre right away

Directions

Apply generously 15 minutes before sun exposure.

Reapply:

- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours

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 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

Other information

Protect this product from excessive heat and direct sun. Report a serious adverse event reaction to: van laere llc. 119 Fifth Avenue, New York, NY 10003

Inactive Ingredients

Water (Aqua), Isononyl Isononanoate, Caprylic/Capric Triglyceride, Dimethicone, Hexylene Glycol, Butyloctyl Salicylate, Cetyl PEG/PPG-10/1 Dimethicone, Argania Spinosa Kernel Extract, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copoly Polyglyceryl-4 Isostearate, Tocopheryl Acetate, Polyhydroxystearic Acid, Squalane, Polyglyceryl-3 -Poyricinoleate, Phenoxyethanol, Lecithin, Sodium Chloride, Isostearic Acid, Hexyl Laurate Ethylhexylglycerin, Bisabolol, Caprylyl Glycol, Polysorbate 60, Chlorphenesin, Disodium EDTA

Distributed by van laere llc, New York, NY10003, USA

PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton

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Chem-Free Active Defense SPF30

1% of proceeds are donated to NYDG Foundation. Committed to health education, preventive care and medical relief in underserved populations.
 1% de nos bénéfices sont reversés au profit de la Fondation NYDG engagée à l'éducation sanitaire, aux soins préventifs et au secours médical auprès de populations mal desservies.
www.nydgfoundation.org

nydg foundation

1 Fl. Oz / 30mL e
www.nydg.com



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 Made in the USA for NYDG / Fabriqué aux États-Unis pour NYDG
 EU Responsible Person: Obelis s.a., 1000 Brussels, Belgium.

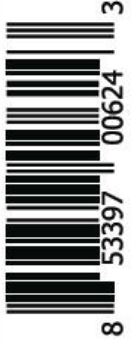
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Chem-Free Active Defense SPF30 / Crème Solaire Défense Active SPF30

For sensitive skin and ideal for sport, this lightweight physical SPF 30 provides broad spectrum UVA/UVB protection for face and body. Water resistant (80 minutes).

Cette crème solaire indice SPF 30 pour peaux sensibles est légère et idéale pour le sport. Elle offre une protection à large spectre des UVA et UVB pour le visage et le corps. Elle résiste à l'eau pendant environ 80 minutes.



Drug Facts	
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Zinc Oxide 17.5%.....	Sunscreen
Uses	
<ul style="list-style-type: none"> • Helps prevent sunburn • Retains SPF after 80 minutes of activity in the water or perspiring 	
Warnings	
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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 swallowed, get medical help or contact a Poison Control Centre right away	
Directions	
Apply generously 15 minutes before sun exposure. Reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours	
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 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	
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CHEM-FREE ACTIVE DEFENSE SPF 30

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71994-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	175 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Isononyl Isononanoate (UNII: S4V5BS6GCX)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Dimethicone (UNII: 92RU3N3Y1O)	
Hexylene Glycol (UNII: KEH0A3F75J)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
ARGAN OIL (UNII: 4V59G5UW9X)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPAS AT 1.5%) (UNII: 86FQE96TZ4)	
Polyglyceryl-4 Isostearate (UNII: 820DPX33S7)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
Squalane (UNII: GW89575KF9)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Isostearic Acid (UNII: X33R8U0062)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
Sodium Chloride (UNII: 451W47IQ8X)	
Hexyl Laurate (UNII: 4CG9F9W01Q)	
Ethylhexylglycerin (UNII: 147D247K3P)	
LEVOMENOL (UNII: 24WE03BX2T)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Chlorphenesin (UNII: I670DAL4SZ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Farnesol (UNII: EB41QIU6JL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71994-007-10	1 in 1 CARTON	05/01/2018	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71994-007-40	1 in 1 CARTON	05/01/2018	
2		120 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	05/01/2018	

Labeler - Van Laere LLC (081010441)

Revised: 2/2018

Van Laere LLC