UV DEFENSE FLUID- titanium dioxide and zinc oxide cream H2O Plus

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.

UV Defense Fluid

Drug Facts

Active ingredient	Purpose		
Zinc Oxide 14%	Sunscreen		
Titanium Dioxide 11%	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
- When using this product keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor if skin rash occurs
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply generously and evenly 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- **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 10 a.m. 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses

Inactive ingredients

Cyclopentasiloxane, Aqua/Water/Eau, Dimethicone, Acrylates/Ethylhexyl Acrylate/Dimethicone Methacrylate Copolymer, Dipropylene Glycol, Isodecyl Isononanoate, Alumina, Stearic Acid, C12-15 Alkyl Benzoate, Sodium Chloride, Aspalathus Linearis Extract, Camellia Sinensis Leaf Extract, Phyllanthus Emblica Fruit Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Undaria Pinnatifida Extract, Tocopherol, Caprylyl Glycol, Dimethicone/PEG-10/15 Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dipotassium Glycyrrhizate, Ferulic Acid, Glycerin, Glyceryl Polyacrylate, Hydrogen Dimethicone, Hydrolyzed Pearl, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Maltodextrin, PEG/PPG18/18 Dimethicone, Propylene Glycol, Sodium Citrate, Sodium Hyaluronate. Tetrahydrodiferuloylmethane. Phenoxyethanol. Potassium Sorbate. Sorbic Acid. Parfum/

Fragrance, Benzyl Salicylate, Hexyl Cinnamal, Limonene, Linalool, CI 77491/Iron Oxides, CI 77492/Iron Oxides (090-20171-000)

Other information

• protect the product in this container from excessive heat and direct sun

Questions or comments?

1-800-242-2284

Distributed by: H2O Plus, L.L.C. Chicago, IL 60607

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

 h_2o^{+TM}

total SOURCETM

Advanced age repair

UV DEFENSE FLUID SPF 50 PA+++

 $30 \text{ mL} / 1 \text{ U.S. Fl oz } \mathbf{e}$

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• reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating • Sun Protection Measures
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Peel back to see additional drug facts ▶

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UV DEFENSE FLUID

titanium dioxide and zinc oxide cream

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:65903-171

Active Ingredient/Active Moiety						
Ingredient Name	Basis of Strength	Strength				
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	11 g in 100 mL				
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	14 g in 100 mL				

Inactive Ingredients	Carrer wale
Ingredient Name	Strength
Aluminum Oxide (UNII: LMI26O6933)	
Water (UNII: 059QF0KO0R)	
Alkyl (C12-15) Benzoate (UNII: A9 EJ3J6 1HQ)	
Green Tea Leaf (UNII: W2ZU1RY8B0)	
Caprylyl Glycol (UNII: 00 YIU5438U)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Dimethicone (UNII: 92RU3N3Y1O)	
Dimethicone/Vinyl Dimethicone Crosspolymer (Hard Particle) (UNII: H895X08VNQ)	
Glycyrrhizinate Dipotassium (UNII: CA2Y0FE3FX)	
Dipropylene Glycol (UNII: E107L85C40)	
Ferulic Acid (UNII: AVM951ZWST)	
Glycerin (UNII: PDC6A3C0OX)	
Calcium Carbonate (UNII: H0G9379FGK)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Isodecyl Isononanoate (UNII: 4X46Q4U00Z)	
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone (UNII: 25G622K2RA)	
Malto dextrin (UNII: 7CVR7L4A2D)	
PEG/PPG-18/18 Dimethicone (UNII: 9H0AO7T794)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Phyllanthus Emblica Fruit (UNII: YLX4CW2576)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Rosemary (UNII: IJ67X351P9)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Hyaluronate Sodium (UNII: YSE9 PPT4TH)	
Sorbic Acid (UNII: X045WJ989B)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Tetrahydrodiferuloylmethane (UNII: 00U0645U03)	
Tocopherol (UNII: R0ZB2556P8)	
Undaria Pinnatifida (UNII: ICV1OK7M1S)	
Benzyl Benzoate (UNII: N863NB338G)	
.AlphaHexylcinnamaldehyde (UNII: 7X6O37OK2I)	
Limonene, (-)- (UNII: 47MAJ1Y2NE)	
Linalool, (+/-)- (UNII: D81QY6I88E)	

Packaging

# Item Code	Package Description	Marke	ting Start Date M	Sarketing End Date				
1 NDC:65903-171-01	30 mL in 1 BOTTLE, WITH APPLICATOR							
Marketing Information								
Marketing Categor		ı Citation	Marketing Start Date	Marketing End Date				
OTC MONOGRAPH NOT F	FINAL part352		04/01/2014					

Labeler - H2O Plus (807722947)

Revised: 4/2014 H2O Plus