

DEFEND HYDRATING BROAD SPECTRUM SPF 15- spf 15 sunscreen cream
Profile 4 Men 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.

Defend Hydrating Broad Spectrum SPF 15

Active Ingredients :

Homosalate.....8.0%	Purpose: Sunscreen
Avobenzone3.0%	
Octisalate.....5.0%	

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.

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- Apply to neck and face before exposure to the sun and the light of day.
- Apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating, reapply at least every two hours.
- Children under 6 months. Ask a doctor.

USE ONLY AS DIRECTED.

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 value of SPF 15 or higher and other sun protection measures including:

- **Limit time in the sun, especially from 10 a.m.-2p.m.**
- **Wear long-sleeved shirts, pants, hats and sunglasses**

Inactive Ingredients

Water/Aqua/Eau, Silica, Caprylic/Capric Triglyceride, Glycerin, Xylitylglucoside, Anhydroxylitol, Xylitol, Chondrus Crispus Extract, Sodium Hyaluronate, Glyceryl Stearate, Butyrospermum Parkii (Shea) Butter, Cetearyl Alcohol, Tocopheryl Acetate, Ilex Paraguariensis Leaf Extract, Avena Sativa

(Oat) Kernel Extract, Vegetable Collagen, Stearic Acid, Polymethyl Methacrylate, Di-C12-15 Alkyl Fumarate, Cetyl Phosphate, Disodium EDTA, Carbomer, Fragrance, Aminomethyl Propanol, Phenoxyethanol, Caprylyl Glycol, Potassium Sorbate, Hexylene Glycol

MADE IN USA OF DOMESTIC AND FOREIGN COMPONENTS

DISTRIBUTED BY:

PROFILE 4 MEN LLC

NAPLES, FL 34108 USA

☐ PROFILE4MEN.COM

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PROFILE®

MEN'S PERFORMANCE GROOMING

DEFEND
HYDRATING
FACIAL SUNSCREEN
BROAD SPECTRUM
SPF 15

75ml e 2.5fl.oz.

DRUG FACTS

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Homosalate 8.0%
Avobenzone 3.0%
Octisalate 5.0%

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Sunscreen

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NAPLES, FL 34108 USA
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spf 15 sunscreen cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70384-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	6 mg in 75 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.25 mg in 75 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3.75 mg in 75 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITYLGLUCOSIDE (UNII: O0IEZ166FB)	
ANHYDROXYLITOL (UNII: 8XWR7NN42F)	
XYLITOL (UNII: VCQ006KQ1E)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
SHEA BUTTER (UNII: K49155WL9Y)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
AVENA SATIVA WHOLE (UNII: 5P8D0Z74RG)	
SOY PROTEIN (UNII: R44IWB3RN5)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHACRYLATE/METHOXY PEG-10 MALEATE/STYRENE COPOLYMER (UNII: 39DK5WQ2PR)	
DI-C12-15 ALKYL FUMARATE (UNII: A1CB3Z898P)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
EDETIC ACID (UNII: 9G34HU7RV0)	
CARBOMER 934 (UNII: Z135WT9208)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	

Product Characteristics

Color	white	Score	
Shape		Size	

Flavor		Imprint Code	
Contains			
Packaging			
#	Item Code	Package Description	Marketing Start Date Marketing End Date
1	NDC:70384-100-01	1 in 1 PACKAGE	04/07/2016
1		75 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	04/07/2016	

Labeler - Profile 4 Men LLC (080080227)

Establishment			
Name	Address	ID/FEI	Business Operations
PhytogenX, Inc.		624386772	manufacture(70384-100)

Revised: 4/2016

Profile 4 Men LLC