

NIVEA MEN SENSITIVE PROTECTIVE- avobenzone, octisalate, octocrylene lotion
Beiersdorf 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.

Nivea Men Sensitive Protective

Active ingredients

Avobenzone 3%

Octisalate 4.7%

Octocrylene 8.4%

Purpose

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

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 Center right away.

Questions or comments?

1-800-227-4703

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply 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 10 a.m.-2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses.
 - children under 6 months of age: Ask a doctor

Inactive ingredients

Water, Isopropyl Palmitate, Glycerin, Tapioca Starch, Cetearyl Alcohol, Glyceryl Stearate Citrate, Tocopheryl Acetate, Panthenol, Chamomilla Recutita (Matricaria) Flower Extract, Hamamelis Virginiana (Witch Hazel) Bark/Leaf Extract, 1,2-Hexanediol, Carbomer, Ethylhexylglycerin, Maltodextrin, Caprylic/Capric Triglyceride, Acrylates/CI0-30 Alkyl Acrylate Crosspolymer, Sodium Hydroxide, Trisodium EDTA, Phenoxyethanol, Piroctone Olamine, Fragrance.

NIVEA MEN
 SENSITIVE
 PROTECTIVE LOTION
 Broad Spectrum SPF 15
 Sunscreen
 Moisturizes and Protects

Drug Facts (continued)

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WWW.NIVEAMENUSA.COM

SENSITIVE

PROTECTIVE LOTION

BROAD SPECTRUM SPF 15

SUNSCREEN
 Moisturizes and Protects

NO DRYING ALCOHOL

2.5 FL. OZ. 75 mL

SENSITIVE PROTECTIVE LOTION BROAD SPECTRUM SPF 15

Skin irritated from shaving?
 Don't tolerate it. It starts with you.

WHAT DO YOU GET?
 This formula is enriched with Vitamin E and natural, soothing Chamomile and Witch Hazel extracts:

- Moisturizes intensively and soothes the skin.
- Improves skin's condition over time.
- Helps protect skin from harmful UVA and UVB rays with Broad Spectrum SPF 15.
- Formulated with no drying alcohol.

RESULT

- Skin looks healthier and cared for.
- Skin is protected and feels comfortable.

SKIN COMPATIBILITY
 DERMATOLOGICALLY TESTED BY MEN
 WITH SENSITIVE SKIN

Beiersdorf
 Made in Mexico
 Distributed by:
 Beiersdorf Inc.
 Wilton, CT 06897

® = reg. tm. of
 Beiersdorf AG, Germany
 88543.790.FA.05 NART # 88543

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Other information

- protect this product from excessive heat and direct sun

NIVEA MEN SENSITIVE PROTECTIVE
 avobenzone, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10356-575
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzonone (UNII: G63QQF2NOX) (Avobenzonone - UNII:G63QQF2NOX)	Avobenzonone	3 g in 100 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	4.7 g in 100 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	8.4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
GLYCERIN (UNII: PDC6A3C0OX)	
STARCH, TAPIOCA (UNII: 24SC3U704I)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
PANTHENOL (UNII: WV9CM0O67Z)	
CHAMOMILE (UNII: FGL3685T2X)	
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)	
HEXANEDIOL (UNII: ZIA319275I)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PIROCTONE OLAMINE (UNII: A4V5C6R9FB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10356-575-16	75 mL in 1 TUBE; Type 0: Not a Combination Product	09/15/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/15/2014	

Labeler - Beiersdorf Inc (001177906)

