

PREVENTAGE FIRMING DEFENSE CREME NORMAL/DRY BROAD SPECTRUM SPF 15- avobenzone, octocrylene cream
Merle Norman Cosmetics, 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.

Preventage Firming Defense Creme Normal/Dry Broad Spectrum SPF 15

Active Ingredients (w/w): Purpose

Avobenzone 1.9%Sunscreen

Octocrylene 9.4% 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

Stop use and ask a doctor if rash occurs.

Directions

For sunscreen use:

apply liberally and evenly 15 minutes before sun exposure

use a water resistant sunscreen if swimming or sweating

reapply at least every 2 hours

children under 6 months: Ask a doctor

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

Apply to cleansed and toned skin prior to sun exposure

Warnings

For external use only

Do not use on damaged or broken skin

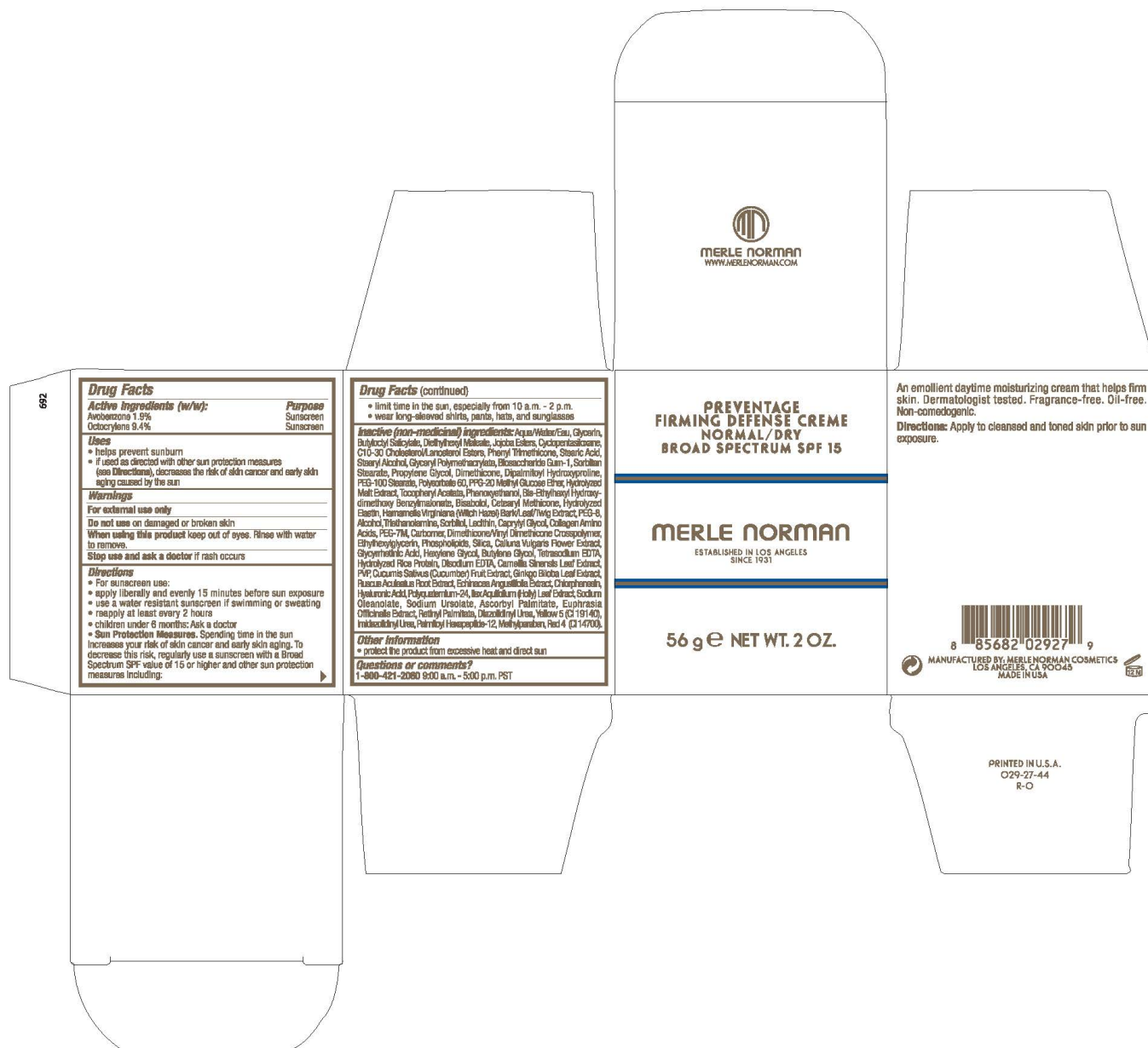
When using this product keep out of eyes. Rinse with water to remove.

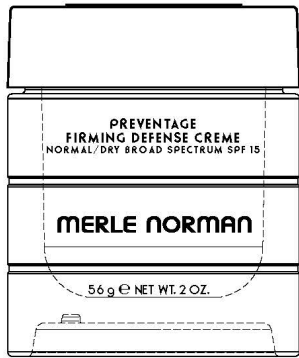
Inactive (non-medicinal) ingredients: Aqua/Water/Eau, Glycerin, Butyloctyl Salicylate, Diethylhexyl Maleate, Jojoba Esters, Cyclopentasiloxane, C10-30 Cholesterol/Lanosterol Esters, Phenyl Trimethicone, Stearic Acid, Stearyl Alcohol, Glyceryl Polymethacrylate, Biosaccharide Gum-1, Sorbitan Stearate, Propylene Glycol, Dimethicone, Dipalmitoyl Hydroxyproline, PEG-100 Stearate, Polysorbate 60, PPG-20 Methyl Glucose Ether, Hydrolyzed Malt Extract, Tocopheryl Acetate, Phenoxyethanol, Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate, Bisabolol, Cetearyl Methicone, Hydrolyzed Elastin, Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, PEG-8, Alcohol, Triethanolamine, Sorbitol, Lecithin, Caprylyl Glycol, Collagen Amino Acids, PEG-

7M, Carbomer, Dimethicone/Vinyl Dimethicone Crosspolymer, Ethylhexylglycerin, Phospholipids, Silica, Calluna Vulgaris Flower Extract, Glycyrrhetic Acid, Glycyrrhetic Acid, Hexylene Glycol, Butylene Glycol, Tetrasodium EDTA, Hydrolyzed Rice Protein, Disodium EDTA, Camellia Sinensis Leaf Extract, PVP, Cucumis Sativus (Cucumber) Fruit Extract, Ginkgo Biloba Leaf Extract, Ruscus Aculeatus Root Extract, Echinacea angustifolia extract, Chlorphenesin, Hyaluronic Acid, Polyquaternium-24, Ilex Aquifolium (Holly) Leaf Extract, Sodium Oleolate, Sodium Ursolate, Ascorbyl Palmitate, Euphrasia Officinalis Extract, Retinyl Palmitate, Diazolidinyl Urea, Yellow 5 (CI 19140), Imidazolidinyl Urea, Palmitoyl Hexapeptide-12, Methylparaben, Red 4 (CI 14700)

Other Information

- protect the product from excessive heat and direct sun





Dermatologist tested.
 Directions: Apply liberally 15 minutes before sun exposure.
 Children under 6 months: Ask a doctor.
 Active Ingredients (w/w): Avobenzone 1.9%, Octocrylene 9.4%.

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.

MANUFACTURED BY: MERLE NORMAN COSMETICS
 LOS ANGELES, CA 90045 MADE IN USA

PREVENTAGE
 FIRING DEFENSE CREME
 NORMAL/DRY BROAD SPECTRUM SPF 15

MERLE NORMAN

56 g e NET WT. 2 OZ.

PREVENTAGE FIRING DEFENSE CREME NORMAL/DRY BROAD SPECTRUM SPF 15

avobenzone, octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57627-203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.9 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9.4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM URSOLATE (UNII: NV5D25VL1O)	
CHLORPHENESIN (UNII: I670DAL4S2)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)	
CUCUMBER (UNII: YY7C30VXJT)	
TROLAMINE (UNII: 9O3K93S3TK)	
GINKGO (UNII: 19FUJ2C58T)	
ENOXOLONE (UNII: P540XA09DR)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

AMINO ACIDS (UNII: 0072R8RF8A)
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POVIDONE (UNII: FZ989GH94E)
HYALURONIC ACID (UNII: S270N0TRQY)
SODIUM OLEANOLATE (UNII: LVB19G8AUT)
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
FD&C RED NO. 4 (UNII: X3W0AM1JLX)
WATER (UNII: 059QF0KO0R)
DIETHYLHEXYL MALEATE (UNII: C2F7JHI12L)
C10-30 CHOLESTEROL/LANOSTEROL ESTERS (UNII: 137SL7IL0Y)
BIOSACCHARIDE GUM-1 (UNII: BB4PU4V09H)
POLYSORBATE 60 (UNII: CAL22UVI4M)
HYDROLYZED BOVINE ELASTIN (BASE; 1000 MW) (UNII: ZR28QKN0WT)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
STEARIC ACID (UNII: 4ELV7Z65AP)
DIMETHICONE (UNII: 92RU3N3Y1O)
PPG-20 METHYL GLUCOSE ETHER (UNII: 3WV1T97D3K)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
LEVOMENOL (UNII: 24WE03BX2T)
CETEARYL METHICONE (15000 MW) (UNII: VY9RTR7MSY)
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)
PEG-100 STEARATE (UNII: YD01N1999R)
CALLUNA VULGARIS FLOWERING TOP (UNII: D9PC510CQV)
EDETATE SODIUM (UNII: MP1J8420LU)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
BASIC YELLOW 5 (UNII: 07BP340B4T)
IMIDUREA (UNII: M629807ATL)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
GLYCERIN (UNII: PDC6A3C0OX)
BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYL MALONATE (UNII: 7D4Q5YJ8NV)
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)
POLYETHYLENE OXIDE 300000 (UNII: 4QIB4U4CQR)
EUPHRASIA STRICTA (UNII: C9642I91WL)
PALMITOYL HEXAPEPTIDE-12 (UNII: HO4ZT5S86C)
METHYL PARABEN (UNII: A2I8C7HI9T)
ILEX AQUIFOLIUM LEAF (UNII: 9Z32IEA9F7)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
ALCOHOL (UNII: 3K9958V90M)
RUSCUS ACULEATUS ROOT (UNII: ZW12V95I1Q)
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:57627-203-01	56 g in 1 JAR; Type 0: Not a Combination Product	11/15/2021	
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/15/2021	

Labeler - Merle Norman Cosmetics, Inc. (008479388)

Establishment

Name	Address	ID/FEI	Business Operations
Merle Norman Cosmetics, Inc.		008479388	manufacture(57627-203)

Revised: 11/2021

Merle Norman Cosmetics, Inc.