

**PREVENTAGE FIRMING DEFENSE CREME NORMAL/DRY MERLE NORMAN-  
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.*

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**Merle Norman Preventage Firming Defense Creme Normal/Dry**

Active Ingredients 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.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if rash occurs.

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.

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:

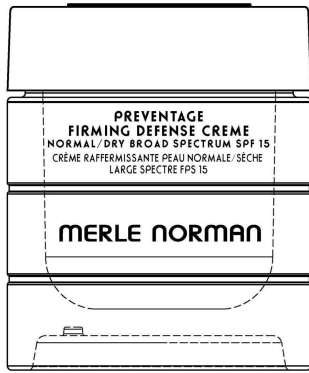
-Limit time in the sun, especially from 10 a.m. – 2 p.m.

-Wear long-sleeved shirts, pants, hats, and sunglasses.

Children under 6 months: Ask a doctor.

Inactive Ingredients: Water (Aqua), Glycerin, Butyloctyl Salicylate, Diethylhexyl Maleate, Jojoba Esters, Cyclopentasiloxane, C10-30 Cholesterol/Lanosterol Esters, Phenyl Trimethicone, Stearic Acid, Stearyl Alcohol, GlycerylPolymethacrylate, Propylene Glycol, Biosaccharide Gum-1, Sorbitan Stearate, PalmitoylOligopeptide, DipalmitoylHydroxyproline, Hydrolyzed Elastin, Collagen Amino Acids, Hydrolyzed Malt Extract, Hydrolyzed Rice Protein, Ilex Aquifolium (Holly) Leaf Extract, Calluna Vulgaris Flower Extract, CucumisSativus (Cucumber) Fruit Extract, Ginkgo Biloba Leaf Extract, RuscusAculeatus Root Extract, Echinacea Angustifolia Extract, Camellia Sinensis Leaf Extract, Glycyrrhetic Acid, HamamelisVirginiana (Witch Hazel) Bark/Leaf/Twig Extract, Hyaluronic Acid, EuphrasiaOfficinalis Extract, Bisabolol, Tocopheryl Acetate, AscorbylPalmitate, RetinylPalmitate, Lecithin, Dimethicone, Dimethicone/Vinyl DimethiconeCrosspolymer, CetearylMethicone, Bis-EthylhexylHydroxydimethoxyBenzylmalonate, PPG-20 Methyl Glucose Ether, PEG-100 Stearate, Polysorbate 60, Sorbitol, Triethanolamine, Alcohol, Caprylyl Glycol, Butylene Glycol, Polyquaternium-24, Sodium Oleanolate, Sodium Ursolate, Phospholipids, PEG-7M, PEG-8, Carbomer,

Silica, PVP, Phenoxyethanol, Chlorphenesin, Methylisothiazolinone, Diazolidinyl Urea, Imidazolidinyl Urea, Methylparaben, Disodium EDTA, Trisodium EDTA, Yellow 5, Red 4



DERMATOLOGIST TESTED.  
**DIRECTIONS:** APPLY TO CLEANSED AND TONED SKIN PRIOR TO SUN EXPOSURE. MODE D'EMPLOI: APPLIQUEZ SUR UNE PEAU PROPRE ET TONIFEE AVANT DE VOUS EXPOSER AU SOLEIL.  
**ACTIVE (MEDICINAL) INGREDIENTS (W/W):** AVOBENZONE 1.9%, OCTOCRYLENE 9.4%

**WARNINGS:** FOR EXTERNAL USE ONLY. NOT TO BE SWALLOWED. AVOID CONTACT WITH EYES. STOP USE AND ASK A DOCTOR IF RASH OR IRRITATION DEVELOPS OR LASTS 15. KEEP OUT OF REACH OF CHILDREN.  
**AVERTISSEMENT:** POUR USAGE EXTERNE UNIQUEMENT. NE PAS AVALER. EVITER LE CONTACT AVEC LES YEUX. ARRÊTER L'UTILISATION ET CONSULTER UN MÉDECIN SI UNE ÉRUPTION OU UNE IRRITATION SE DÉVELOPPE OU DURE. NE PAS LAISSER À LA PORTÉE DES ENFANTS.

56 g e NET WT. 2 OZ.

MERLE NORMAN COSMETICS  
 LOS ANGELES, CA 90045 MADE IN USA

**PREVENTAGE FIRMING DEFENSE CREME NORMAL/ DRY BROAD SPECTRUM SPF 15**  
 CREME RAFFERMISSANTE PEAU NORMALE/ SECHE LARGE SPECTRE FPS 15

**MERLE NORMAN**

**Drug Facts** (continued)

**Inactive Ingredients:** Water (Aqua), Glycerin, Butyloctyl Salicylate, Dimethylhexyl Maleate, Jojoba Esters, Cyclopentasiloxane, C10-30 Cholesterol/lanosterol Esters, Phenyl Trimethicone, Stearic Acid, Stearyl Alcohol, Glyceryl Polymethacrylate, Propylene Glycol, Biosaccharide Gum-1, Sorbitan Stearate, Palmitoyl Oligopeptide, Dipalmitoyl Hydroxyproline, Hydrolyzed Elastin, Collagen Amino Acids, Hydrolyzed Malt Extract, Hydrolyzed Rice Protein, Ilex Aquifolium (Holly) Leaf Extract, Calluna Vulgaris Flower Extract, Cucumis Sativus (Cucumber) Fruit Extract, Ginkgo Biloba Leaf Extract, Ruscus Aculeatus Root Extract, Echinacea Angustifolia Extract, Camellia Sinensis Leaf Extract, Glycyrrhizic Acid, Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Hyaluronic Acid, Euphrasia Officinalis Extract, Bisabolol, Tocopheryl Acetate, Ascorbyl Palmitate, Retinyl Palmitate, Lecithin, Dimethicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Cetearyl Methicone, Bis-ethylhexyl Hydroxydimethoxy Benzylmalonate, PPG-20 Methyl Glucose Ether, PEG-100 Stearate, Polysorbate 60, Sorbitol, Triethanolamine, Alcohol, Caprylyl Glycol, Butylene Glycol, Polyquaternium-24, Sodium Oleoate, Sodium Ursolate, Phospholipids, PEG-7M, PEG-8, Carbomer, Silica, PVP, Phenoxyethanol, Chlorphenesin, Methylisothiazolinone, Diazolidinyl Urea, Imidazolidinyl Urea, Methylparaben, Disodium EDTA, Trisodium EDTA, Yellow 5, Red 4 012412.

**Other information** Protect the product from excessive heat and direct sun.

**Questions or comments?** 1-800-421-2060 9:00 am to 5:00 pm PST

AN EMOLLIENT DAYTIME MOISTURIZING CREAM THAT HELPS FIRM SKIN. PROTECTS SKIN FROM ENVIRONMENTAL STRESSORS WITH AN ANTI-POLLUTION COMPLEX. DERMATOLOGIST TESTED. NON-COMEDOGENIC. OIL-FREE. FRAGRANCE-FREE.

**DIRECTIONS:** APPLY TO CLEANSED AND TONED SKIN PRIOR TO SUN EXPOSURE.



MERLE NORMAN COSMETICS  
 LOS ANGELES, CA 90045  
 MADE IN USA



**PREVENTAGE FIRMING DEFENSE CREME NORMAL/ DRY BROAD SPECTRUM SPF 15**

**MERLE NORMAN**

ESTABLISHED IN LOS ANGELES SINCE 1931

56 g e NET WT. 2 OZ.

**Drug Facts**

Active Ingredients	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.

**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** 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: Ask a doctor.

Preventage Firming Defense creme

Broad Spectrum SPF 15

Merle Norman established in Los Angeles since 1931

56 g Net Wt. 2 Oz

<b>PREVENTAGE FIRMING DEFENSE CREME NORMAL/ DRY MERLE NORMAN</b>			
avobenzone, octocrylene cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57627-121
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name		Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	1.064 g in 56 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	5.264 g in 56 g
<b>Inactive Ingredients</b>			
Ingredient Name			Strength

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>DIETHYLHEXYL MALEATE</b> (UNII: C2F7JHI2L)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THF5PCI0R)	
<b>C10-30 CHOLESTEROL/LANOSTEROL ESTERS</b> (UNII: 137SL7IL0Y)	
<b>PHENYL TRIMETHICONE</b> (UNII: DR0K5NOJ4R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4HIY)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>BIO SACCHARIDE GUM-1</b> (UNII: BB4PU4V09H)	
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	
<b>PALMITOYL OLIGOPEPTIDE</b> (UNII: HO4ZT5S86C)	
<b>DIPALMITOYL HYDROXYPROLINE</b> (UNII: E6AHA53N1H)	
<b>HYDROLYZED ELASTIN, BOVINE, ALKALINE (1000 MW)</b> (UNII: ZR28QKN0WT)	
<b>ILEX AQUIFOLIUM LEAF</b> (UNII: 9Z32IEA9F7)	
<b>CALLUNA VULGARIS FLOWERING TOP</b> (UNII: D9PC510CQV)	
<b>CUCUMBER</b> (UNII: YY7C30VXJT)	
<b>GINKGO</b> (UNII: 19FUJ2C58T)	
<b>RUSCUS ACULEATUS ROOT</b> (UNII: ZW12V95I1Q)	
<b>ECHINACEA ANGUSTIFOLIA ROOT</b> (UNII: D982V7VT3P)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>ENOXOLONE</b> (UNII: P540XA09DR)	
<b>HYALURONIC ACID</b> (UNII: S270N0TRQY)	
<b>EUPHRASIA STRICTA</b> (UNII: C9642I91WL)	
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYL MALONATE</b> (UNII: 7D4Q5YJ8NV)	
<b>PPG-20 METHYL GLUCOSE ETHER</b> (UNII: 3WV1T97D3K)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>SODIUM OLEANOLATE</b> (UNII: LVB19G8AUT)	
<b>SODIUM URSOLATE</b> (UNII: NV5D25VL1O)	
<b>POLYETHYLENE GLYCOL 300000</b> (UNII: 4QIB4U4CQR)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>IMIDUREA</b> (UNII: M629807ATL)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	

<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>EDETATE TRISODIUM</b> (UNII: 420IP921MB)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57627-121-02	1 in 1 BOX	08/17/2012	
1	NDC:57627-121-01	56 g in 1 JAR; 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	08/17/2012	

**Labeler** - Merle Norman Cosmetics, Inc (008479388)

**Registrant** - Merle Norman Cosmetics, Inc (008479388)

### Establishment

Name	Address	ID/FEI	Business Operations
Merle Norman Cosmetics, Inc		008479388	manufacture(57627-121)

Revised: 1/2020

Merle Norman Cosmetics, Inc