

DAILY FACIAL MOISTURIZER BROAD SPECTRUM SPF15 SUNSCREEN- avobenzone, octocrylene cream

Emilia Personal Care 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.

America's Choice® daily facial moisturizer

Active ingredients

Avobenzone 3.0%

Octocrylene 10.0%

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.

Directions

Apply liberally 15 minutes before sun exposure.

Use a water resistant sunscreen if swimming or sweating

Reapply at least every 2 hours

Children under 6 months of age: 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

Other Information

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

Inactive ingredients

water, diisopropyl adipate, cyclopentasiloxane, glycerin, glyceryl stearate, PEG-100 stearate, titanium dioxide, alumina, simethicone, cetyl alcohol, polymethyl methacrylate, phenoxyethanol, triethanolamine, benzyl alcohol, xanthan gum, acrylates/C10-30 alkyl acrylate crosspolymer, tocopheryl acetate (vitamin E), carbomer, potassium cetyl phosphate, disodium EDTA.

Package/Label Principal Display Panel

America's Choice[®] daily facial moisturizer

non-greasy and lightweight

non-comedogenic

(won't clog pores)

fragrance-free & paba-free

dermatologist tested

*Compare to Cetaphil[®] Daily Facial Moisturizer SPF 15 ingredients

BROAD SPECTRUM SPF15 SUNSCREEN

UVA/UVB PROTECTION

4 FL OZ (118 mL)

*This product is not manufactured or distributed by Galderma[®], owner of the registered trademark Cetaphil[®]

DISTRIBUTED BY ONPOINT, INC.

2 PARAGON DRIVE

MONTVALE, NJ 07645

Manufactured in Israel 2T326 AD C1



daily facial moisturizer

Drug Facts

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Avobenzone 3.0%	Sunscreen
Octocrylene 10.0%	Sunscreen

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daily facial moisturizer



daily facial moisturizer

- non-greasy and lightweight
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*Compare to Cetaphil® Daily Facial Moisturizer SPF 15 in ingredients

BROAD SPECTRUM **SPF 15** **SUNSCREEN**

UVA/UVB PROTECTION

4 FL OZ (118 mL)

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 2 PARAGON DRIVE
 MONTVALE, NJ 07045
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 Manufactured in Israel 27326 AD C1

Carton Label

DAILY FACIAL MOISTURIZER BROAD SPECTRUM SPF15 SUNSCREEN
 avobenzone, octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42421-326
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
PEG-100 STEARATE (UNII: YD01N1999R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALUMINUM OXIDE (UNII: LM26O6933)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLY(METHYL ACRYLATE-CO-METHYL METHACRYLATE-CO-METHACRYLIC ACID 7:3:1; 280000 MW) (UNII: 99Q3C7L77T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TROLAMINE (UNII: 9O3K93S3TK)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42421-326-11	1 in 1 CARTON		
1		118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/10/2014	

