FACE PLUS SCALP INVISIBLE DAILY SPF 30 BROAD SPECTRUM- avobenzone, homosalate, octisalate, and octocrylene gel Mantl

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.

Face + Scalp Invisible Daily SPF 30 Broad Spectrum

Drug Facts

Active Ingredient	Purpose
Avobenzone 3%	Sunscreen
Homosalate 15%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 2.8%	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
- Reapply at least every 2 hours. Use a water resistant sunscreen if swimming or sweating.
- **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

Isododecane, Dimethicone/Bis-Isobutyl PPG-20 Crosspolymer, Caprylic/Capric Triglyceride, Dicaprylyl Ether, Butyloctyl Salicylate, Epilobium Angustifolium Flower/Leaf/Stem Extract, Zingiber Officinale (Ginger) Root Extract, Tocopherol, Bisabolol, Linoleic Acid, Linolenic Acid, Silica, Water/Aqua/Eau, Sodium Metabisulfite, Phenoxyethanol, Fragrance (Parfum)

Other Information

Protect this product from excessive heat and direct sun.

Dist. by Mantl, Inc. Tustin, CA 92780

PRINCIPAL DISPLAY PANEL - 98 ml Bottle Label

MANTL™

FACE + SCALP

Invisible Daily SPF 30

BROAD SPECTRUM

3.3 fl oz / 98 ml

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avobenzone, homosalate, octisalate, and octocrylene gel

Product Information				
Product Type	HUMAN OTC DRUG Item Code (Source) NDC:73434-001		NDC:73434-001	
Route of Administration	Route of Administration TOPICAL			
Active Ingredient/Active	Molety			
Ingredient Name			Basis of Streng	gth Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)			AVOBENZ ONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)			HOMOSALATE	150 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)			OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) OCTOCRYLE				28 mg in 1 mL

Strength
469.2765 mg in 1 mL

F	Packaging			
#	ttem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73434- 001-98	98 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/05/2020	
2	NDC:73434- 001-30	30 mL in 1 TUBE; Type 0: Not a Combination Product	01/05/2020	09/07/2023

Markating	Information
Marketing	Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC MONOGRAPH FINAL	part352	01/05/2020	

Labeler - Mantl (076670408)

Registrant - Cosmetic Lab Inc. (196409143)

Establishment			
Name	Address	ID/FEI	Business Operations
Cosmetic Lab Inc.		196409143	manufacture(73434-001, 73434-001)

Revised: 8/2023