CALMING PRIMER SPF 20- titanium dioxide and zinc oxide liquid Colorescience

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.

Calming Primer SPF 20

Drug Facts

Active ingredients	Purpose
Titanium Dioxide 5.4%	Sunscreen
Zinc Oxide 5.4%	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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure. Works best on moisturized skin.
- Reapply:
 - After 40 minutes of swimming or sweating.
 - Immediately after towel drying.
 - 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.

Inactive ingredients

Cyclopentasiloxane, Caprylic/Capric Triglyceride, Dimethicone Crosspolymer, Glycerin, Water, Dimethicone/Vinyl Dimethicone Crosspolymer, Cucumis Sativus (Cucumber) Fruit Extract, Spirulina Maxima Extract, Camellia Sinensis Leaf Extract, Opuntia Ficus-Indica Stem Extract, Palmaria Palmata Extract, Disodium Lauriminodipropionate Tocopheryl Phosphates, Citrus Paradisi (Grapefruit) Seed Extract, Ascorbic Acid, Dimethiconol, Dimethicone, Triethoxycaprylylsilane, Benzoic Acid, Dehydroacetic Acid, Phenoxyethanol, Iron Oxides (CI 77491, CI 77492, CI 77499)

Other information

Protect this product from excessive heat and direct sun.

Questions or comments?

Call toll free 866.426.5673

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

colorescience®

CALMING PRIMER

3-IN-1 FACE PRIMER

Neutralizes redness

Soothes & nourishes skin

Extends makeup wear

20 Broad Spectrum SPF 20 Sunscreen

CHEMICAL-FREE ACTIVES | 100% MINERAL WATER/SWEAT RESISTANT (40 MINUTES)

1 fl. oz. / 30 mL

CALMING PRIMER For USA only For USA only **Drug Facts** Drug Facts (continued) Active Ingredients Purpose Inactive ingredients: Titanium Dioxide 5.4% Cyclopentasiloxane, Caprylic/Capric Triglyceride, Dimethicone Sunscreen Zinc Oxide 5.4%Sunscreen Crosspolymer, Glycerin, Water, Uses Dimethicone/Vinyl Dimethicone Helps prevent sunburn. If used as directed with other sun (Cucumber) Fruit Extract, Spirulina protection measures (see Directions), Maxima Extract, Camellia Sinensis decreases the risk of skin cancer and Leaf Extract, Opuntia Ficus-Indica early skin aging caused by the sun. Stem Extract, Palmaria Palmata formulas designed to fit your life at Extract, Disodium Warnings Lauriminodipropionate Tocopheryl For external use only. Phosphates, Citrus Paradisi Do not use on damaged or broken skin. When using this product keep out of Acid, Dimethiconol, Dimethicone, Dispense half a pump to fingertips. **CALMING** eyes. Rinse with water to remove. Triethoxycaprylylsilane, Benzoic Acid, Stop use and ask a dootor if rash occurs. Dehydroacetic Acid, Phenoxyethanol, Iron Oxides (Cl 77491, Cl 77492, **PRIMER** swallowed, get medical help or contact a Poison Control Center right away. Other Information: 3-IN-1 FACE PRIMER Apply liberally 15 minutes before sun • · Protect this product from excessive to not stay too long in the sun, eve ep bables and young children ou = Reapply: Neutralizes redness Questions or comments? = After 40 minutes of swimming Soothes & nourishes skin Immediately after towel drying. ducing the quantity of sunscreen Ingredients (EU) Extends makeup wear . At least every 2 hours. oduct applied will lower the level Cyclopentasiloxane, Caprylic/Capric Children under 6 months; ask a doctor protection significantly. Generously = Sun Proteotion Measures Dimethicone/Vinyl Dimethicone your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum Leaf Extract, Opuntia Ficus-Indica Stem Broad Spectrum SPF value of 15 or higher and other SPF 20 Sunscreen = Limit time in the sun, especially Phosphates, Citrus Paradisi Seed Extract, from 10 a.m.-2 p.m. Wear long-sleeved shirts, pants, CHEMICAL-FREE ACTIVES | 100% MINERAL Triethoxycaprylylsllane, Benzoic Acid, WATER/SWEAT RESISTANT (40 MINUTES) Dehydroacetic Acid, Phenoxyethanol, 1 fl. oz. / 30 mL Continued on opposite side panel 0.94531

Quiet The Sto m

Neutralize redness, seethe skin and extend makeup wear while

zinc oxide and titanium dioxide

deliver non-chemical UVA/UVB

protection. Colorescience® Calming Primer SPF 20 provides

uncompromising, health-forward

ot product around the face and

end, ensuring even coverage.

Can be worn alone or under your

nile using a sunscreen product.

e sun is a serious health threat.

Manufactured for / Fabriqué

sunscreen and environmental

daily confidence in a whipped,

universal golden-nude shade.

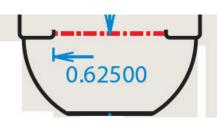
Discover our full line of

colorescience.com

Tavorite foundation.

to Use (EU)

How to Use



CALMING PRIMER SPF 20

titanium dioxide and zinc oxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68078-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	54 mg in 1 mL	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	54 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
Cyclomethicone 5 (UNII: 0THT5PCI0R)		
Dimethicone Crosspolymer (450000 MPA.S AT 12% IN Cyclopentasiloxane) (UNII: UF7620L1W6)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
Water (UNII: 059QF0KO0R)		
Glycerin (UNII: PDC6A3C0OX)		
Dimethicone (UNII: 92RU3N3Y10)		
Disodium Lauriminodipropionate Tocopheryl Phosphates (UNII: 0K5Y9U1P6M)		
Dimethiconol (100000 CST) (UNII: OSA9UP217S)		
ARTHROSPIRA MAXIMA (UNII: 9K7IG15M0Q)		
FERRIC OXIDE YELLOW (UNII: EX43802MRT)		
Citrus Paradisi Seed (UNII: 12F08874Y7)		
Phenoxyethanol (UNII: HIE492ZZ3T)		
Triethoxycaprylylsilane (UNII: LDC331P08E)		
Ascorbic Acid (UNII: PQ6CK8PD0R)		
Green Tea Leaf (UNII: W2ZU1RY8B0)		
PALMARIA PALMATA (UNII: 7832HOY4ZQ)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
Opuntia Ficus-Indica Stem (UNII: MUD8892KHL)		
FERROSOFERRIC OXIDE (UNII: XM0M87F357)		
Benzoic Acid (UNII: 8SKN0B0MIM)		
Dehydroacetic Acid (UNII: 2KAG279R6R)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68078-040- 01	1 in 1 CARTON	01/01/2020	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2020	
Tilla			

Labeler - Colorescience (128731929)

Revised: 10/2021 Colorescience