

ONE AND DONE- spf 40 cream
Thirteen Lune 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.

Active Ingredient

ZINC OXIDE 1%

TITANIUM DIOXIDE 2%

Purpose

SUNSCREEN

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.

Keep outer carton for complete labeling information.

Uses

Helps prevent sunburn.

If used as directed with other sun protection measures (See Directions), decrease the risk of skin cancer and early skin aging caused by the sun.

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 increased your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad

spectrum SPF of 15 or higher and other sun protection measure including:

- Limit time in the sun, especially from 10 a.m. - 2p.m.
- Wear long sleeve shirts, pants, hats and sunglasses.

Children under 6 months: Ask a doctor

Questions

(888) 305-2032

Inactive Ingredients

Water, Butyloctyl Salicylate, Octyldodecyl Neopentanoate, Ethylhexyl Isononanoate, Polyester-7, Glycerin, Neopentyl Glycol Diheptanoate, Niacinamide, Cetyl Alcohol, Glyceryl Stearate, Squalane, PEG-75 Stearate, Phenoxyethanol, Bisabolol, Hydrolyzed Sodium Hyaluronate, Pyrus Malus (Apple) Fruit Extract, C12-15 Alkyl, Benzoate, Lysolecithin, Sclerotium Gum, Dimethiconol/Caprylylsilsesquioxane/Silicate Crosspolymer, Allantoin, Caprylyl Glycol, Hippophae Rhamnoides Seed Oil, Prunus, Domestica Seed Oil, Mauritia Flexuosa Fruit Oil, Triceteareth-4 Phosphate, Pullulan, Xanthan Gum, Ceteth-20, Steareth-20, Ethylhexylglycerin, Hexylene Glycol, Sodium Hyaluronate, Trilaureth-4 Phosphate, Butylene Glycol, Disodium EDTA, Dimethiconol/Propylsilsesquioxane/Silicate Crosspolymer, Plankton Extract, Lecithin, Silica, Avena Sativa (Oat) Kernel Extract, Kigelia Africana Fruit Extract, Camellia Sinensis Leaf Extract, Potassium Sorbate, Sodium Ascorbate, Tocopherol.

KEEP OUT OF REACH OF CHILDREN.

Principal Display Panel

RELEVANT

YOUR SKIN SEEN

ONE & DONE

Everyday Cream
with R-Rev Complex
Crème Quotidienne

Broad Spectrum SPF 40
Sunscreen

1.7 fl oz | 50 ml

Active ingredient

Active ingredient	Purpose
Zinc Oxide 1%.....	Sunscreen
Titanium Dioxide 2%.....	Sunscreen

Purpose

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MADE IN THE USA WITH GLOBALLY
SOURCED INGREDIENTS
FAIT AUX ÉTATS-UNIS AVEC DES INGRÉDIENTS
PROVENANT DE PARTOUT DANS LE MONDE

DIST. BY: THIRTEEN LUNE, INC.
WEST HOLLYWOOD, CA 90069



TUBE



PUMP/CAP

Non Printing Area

5mm(3/16")

RELEVANT

YOUR SKIN SEEN

ONE & DONE

Everyday Cream
with R-Rev Complex
Crème Quotidienne

Broad Spectrum SPF 40
Large Spectre FPS 40

0.5 fl oz | 15ml

3mm(1/8")

H1

Active ingredient | Purpose

Zinc Oxide 1%.....Sunscreen
Titanium Dioxide 2%.....Sunscreen

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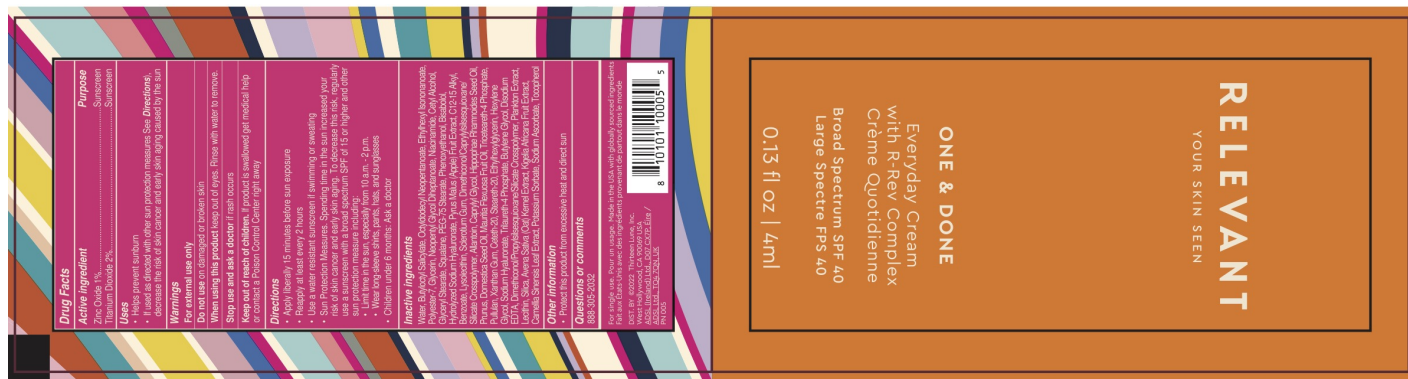
DIST. BY: THIRTEEN LUNE, INC.
WEST HOLLYWOOD, CA 90069
PN201



H2

Non Printing Area

15ML RELEVANT ONE + DONE SPF



4ML RELEVANT ONE + DONE SACHET (SAMPLE)

ONE AND DONE

spf 40 cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82735-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	1 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82735-200-01	50 mL in 1 TUBE; Type 0: Not a Combination Product	05/30/2022	
2	NDC:82735-200-02	15 mL in 1 TUBE; Type 0: Not a Combination Product	06/15/2022	
3	NDC:82735-200-03	4 mL in 1 PACKET; Type 0: Not a Combination Product	06/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/30/2022	

