

NATUROPATHICA- zinc oxide lotion

Bentley Laboratories, LLC

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.

NATUROPATHICA CALENDULA ESSENTIAL HYDRATING LOTION

Drug Facts

Active Ingredient

Zinc Oxide 15.002%

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 product is swallowed, get medical help or contact a Poison

Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply at least every two 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 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10a.m. - 2p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses
 - children under 6 months of age: consult a doctor

Other Information

Protect the product in this container from excessive heat and direct sun

Questions or Comments? call toll free 646-979-3997

Inactive Ingredients

Aqua/Water/Eau,
Coco-Caprylate/Caprato, C12-15 Alkyl Benzoate,
Galactarabinan, Glycerin, Triethyl Citrate,
Cetearyl Alcohol, Behenyl Alcohol, Butyloctyl
Salicylate, Propanediol, Cetearyl Glucoside,
Carthamus Tinctorius (Safflower) Oleosomes, Sodium
Stearoyl Glutamate, Lavandula Angustifolia
(Lavender) Oil, Lavandula Angustifolia (Lavender)
Flower/Leaf/Stem Extract, Rosa Damascena Flower
Oil, Tagetes Minuta Flower Oil, Citrus Aurantium Dulcis
(Orange) Flower Oil, Ethyl Ferulate, Undaria
Pinnatifida Extract, Polyglyceryl-3 Polyricinoleate,
Glyceryl Caprylate, Borago Officinalis Seed Oil,
Hydroxyacetophenone, Xylitylglucoside,
Coco-Glucoside, Bisabolol, Xanthan Gum, Isostearic
Acid, Anhydroxylitol, Citric Acid, Xylitol,
Caprylhydroxamic Acid, Polygonum Aviculare Extract,
Potassium Sorbate, Sodium Benzoate, Carthamus
Tinctorius (Safflower) Seed Oil, Calendula Officinalis
Flower Extract, Trehalose, Xanthophylls

Product Label

NATUROPATHICA®

FOR DEEPER BEAUTY

CALENDULA

ESSENTIAL

HYDRATING LOTION

BROAD SPECTRUM

SPF 30 SUNSCREEN

FLUIDE ESSENTIAL

HYDRATANT

1.7 FL. OZ /50 ML

Distributed by:

Naturopathica Holistic Health

New York, NY 10001. Dublin, Ireland

Naturopathica.com 646-979-3997

1.7 FLOZ



This nourishing lotion features calming calendula to deliver instant, soothing hydration for soft, supple skin. Its non-whitening micronized zinc protects from UVA/UVB rays, premature aging, and future damage, including the risk of skin cancer.

Perfect for all skin types

How to Use: Apply a generous amount to the face and neck 15 minutes before sun exposure. Reapply every 2 hours. Avoid contact with eyes.

KEY INGREDIENTS

Calendula: An ancient herb that deeply nourishes and soothes the skin

Knotgrass: This antioxidant rich botanical helps visibly improve the texture and appearance of damaged skin

Micronized Zinc Oxide: This coral reef safe ingredient provides a physical barrier that blocks UVA/UVB rays

DRUG FACTS

Active Ingredient Zinc Oxide 15.002%

Purpose: Sunscreen

Use this to 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.

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:
• apply liberally 15 minutes prior to sun exposure
• reapply at least every two 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 protecting measures including:
• limit time in the sun, especially from 10am-3pm
• wear long-sleeved shirts, pants, hats and sunglasses
• children under 6 months of age consult a doctor

Other information: protect the product in this container from excessive heat and direct sun

Questions or Comments? call toll free 844-974-3997

Inactive Ingredients: Aqua/Water/Sea, Coco-Caprylate/Caprate, C12-15 Alkyl Benzoate, Simmondsium Oleum, Triethyl Citrate, Calcium Nitrate, Behenyl Alcohol, Butylbutyl Stearate, Propylene Glycol, Carbonyl Diacrylate, Carthamus Tinctorius (Safflower) Oleosomes, Sodium Stearyl Glucamate, Lavandula Angustifolia (Lavender) Oil, Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, Rosa Damascena Flower Oil, Tagetes Minuta Flower Oil, Citrus Aurantium Dulcis (Orange) Flower Oil, Citrus Ferox, Linum, Pennantia Extract, Polyhydroxyethyl Methacrylate, Glyceryl Caprylate, Borago Officinalis Seed Oil, Hydroxyacetophenone, Xanthoxanthin, Crocodylacetate, Shikoni, Xanthan Gum, Inositol, Ascorbyl Tetraisorbate, Citric Acid, Xanthan, Capryl Glycol, Polyglyceryl-3 Polydistearate, Potassium Sorbate, Sodium Benzoate, Carthamus Tinctorius (Safflower) Seed Oil, Calendula Officinalis Flower Extract, Inulin, Xanthan.



Ce fluide nourrissant est enrichi au calendula apaisant pour hydrater instantanément et laisser la peau douce et saine. L'oxyde de zinc micronisé, ne laissant pas de trace blanche, protège la peau des rayons UVA et UVB, du vieillissement prématuré et des dommages futurs, dont les risques de cancer de la peau.

Convient à tout type de peaux

Mode d'emploi: Appliquer en couche généreuse sur le visage et le cou 15 minutes avant l'exposition au soleil. Renouveler toutes les 2 heures. Éviter le contact avec les yeux.

INGRÉDIENTS PRINCIPAUX

Calendula: Une herbe traditionnelle qui apaise et nourrit la peau en profondeur

Renouée: Cette plante, riche en antioxydants, aide à améliorer visiblement la texture et l'apparence des peaux abîmées

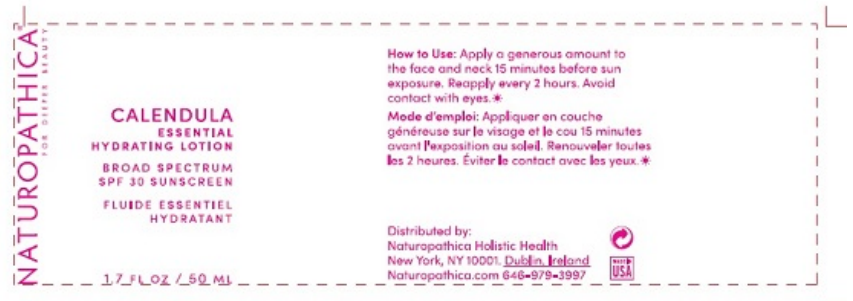
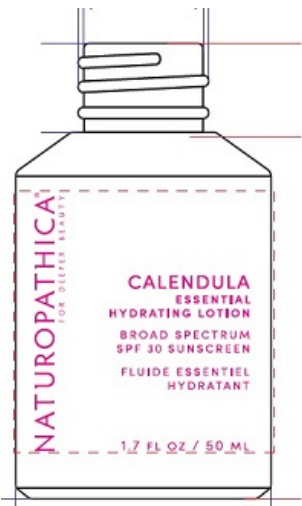
Oxyde de zinc micronisé: Cet ingrédient respectueux des récifs coralliens, offre une barrière physique bloquant les rayons UVA et UVB

Distributed by:
Naturopathica Holistic Health
New York, NY 10001, Dublin, Ireland
Naturopathica.com 646-974-3997
Made from 100% Post-Consumer Waste Recycled Fibers

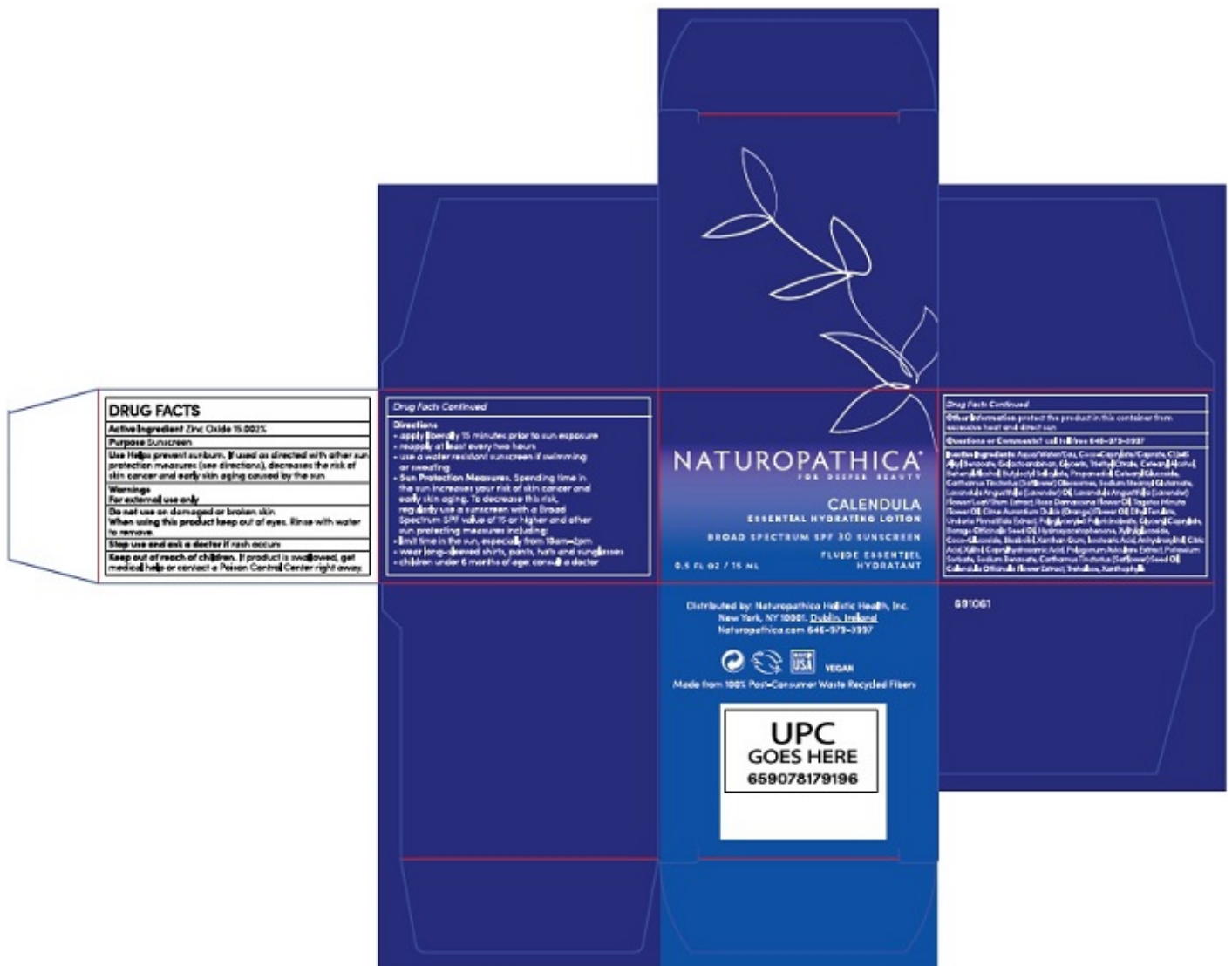


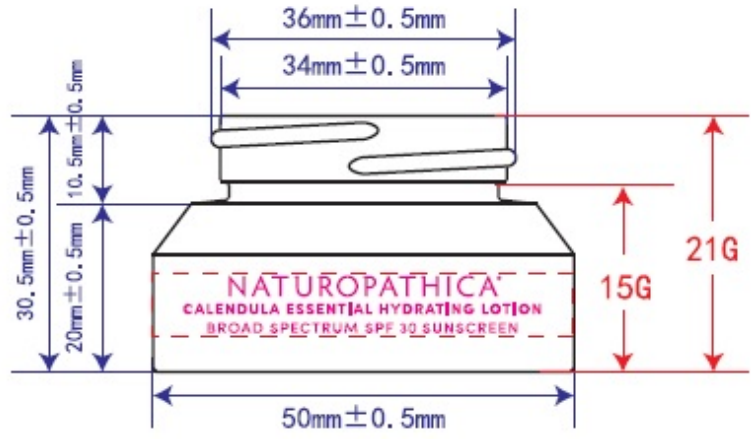
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0.5 FL OZ





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NATUROPATHICA			
zinc oxide lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54111-152
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)		ZINC CATION	15.002 g in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0KO0R)			
CO CO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
GALACTOARABINAN (UNII: SL4SX1O487)			
GLYCERIN (UNII: PDC6A3C0OX)			
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
DOCOSANOL (UNII: 9G1OE216XY)			
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)			
PROPANEDIOL (UNII: 5965N8W85T)			
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)			
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)			

SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)
LAVENDER OIL (UNII: ZBP1YXW0H8)
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)
ROSA DAMASCENA FLOWER OIL (UNII: 18920M3T13)
TAGETES MINUTA FLOWER OIL (UNII: 1T0ZMU8M8B)
CITRUS SINENSIS FLOWER OIL (UNII: AJ56JP5TFP)
ETHYL FERULATE (UNII: 5B8915UELW)
UNDARIA PINNATIFIDA (UNII: ICV1OK7M1S)
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)
BORAGE SEED OIL (UNII: F8XAG1755S)
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)
XYLITYLGLUCOSIDE (UNII: O0IEZ166FB)
COCO GLUCOSIDE (UNII: ICS790225B)
LEVOMENOL (UNII: 24WE03BX2T)
XANTHAN GUM (UNII: TTV12P4NEE)
ISOSTEARIC ACID (UNII: X33R8U0062)
ANHYDROXYLITOL (UNII: 8XWR7NN42F)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
XYLITOL (UNII: VCQ006KQ1E)
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
SODIUM BENZOATE (UNII: OJ245FE5EU)
SAFFLOWER OIL (UNII: 65UEH262IS)
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
TREHALOSE (UNII: B8WCK70T7I)
LUTEIN (UNII: X72A60C9MT)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54111-152-50	1 in 1 CARTON	01/31/2021	
1		50 mL in 1 JAR; Type 0: Not a Combination Product		
2	NDC:54111-152-51	1 in 1 CARTON	01/31/2021	
2		15 mL 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	part347	01/31/2021	

Labeler - Bentley Laboratories, LLC (068351753)