

**NATUROPATHICA CALENDULA AND BUTTERFLY GINGER SPF 40- zinc oxide cream**  
**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.*

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**NATUROPATHICA CALENDULA & BUTTERFLY GINGER EYE CREAM**

**Drug Facts**

**Active Ingredient**

Zinc Oxide 19.92375%

**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:** Water (Aqua), Coco-Caprylate/Caprates, Glycerin, Galactarabinan, Butyloctyl Salicylate, Griffonia Simplicifolia Seed Extract, Cetearyl Alcohol, Propanediol, Caprylic/Capric Triglyceride, Undaria Pinnatifida Extract, Polyglyceryl-3 Polyricinoleate, Hydrogenated Lecithin, Palmitic Acid, 1,2-Hexanediol, Borago Officinalis Seed Oil, Caprylyl Glycol, Hydrolyzed Vegetable Protein, Xylitylglucoside, Isostearic Acid, Cetearyl Glucoside, Xanthan Gum, Anhydroxylitol, Citric Acid, Trehalose, Camellia Sinensis Leaf Extract, Lactobacillus Ferment Lysate, Punica Granatum Flower Extract, Xylitol, Polyhydroxystearic Acid, Lecithin, Hedychium Coronarium Root Extract, Lactobacillus Ferment, Leuconostoc/Radish Root Ferment Filtrate, Polygonum Aviculare Extract, Caffeine, Potassium Sorbate, Sodium Benzoate, Carthamus Tinctorius (Safflower) Seed Oil, Calendula Officinalis Flower Extract, Xanthophylls

## **Product Label**

**NATUROPATHICA®**

**FOR DEEPER BEAUTY**

**CALENDULA &**

**BUTTERFLY GINGER**

**EYE CREAM**

**BROAD SPECTRUM SPF 40 SUNSCREEN**

**FLUIDE ESSENTIAL**

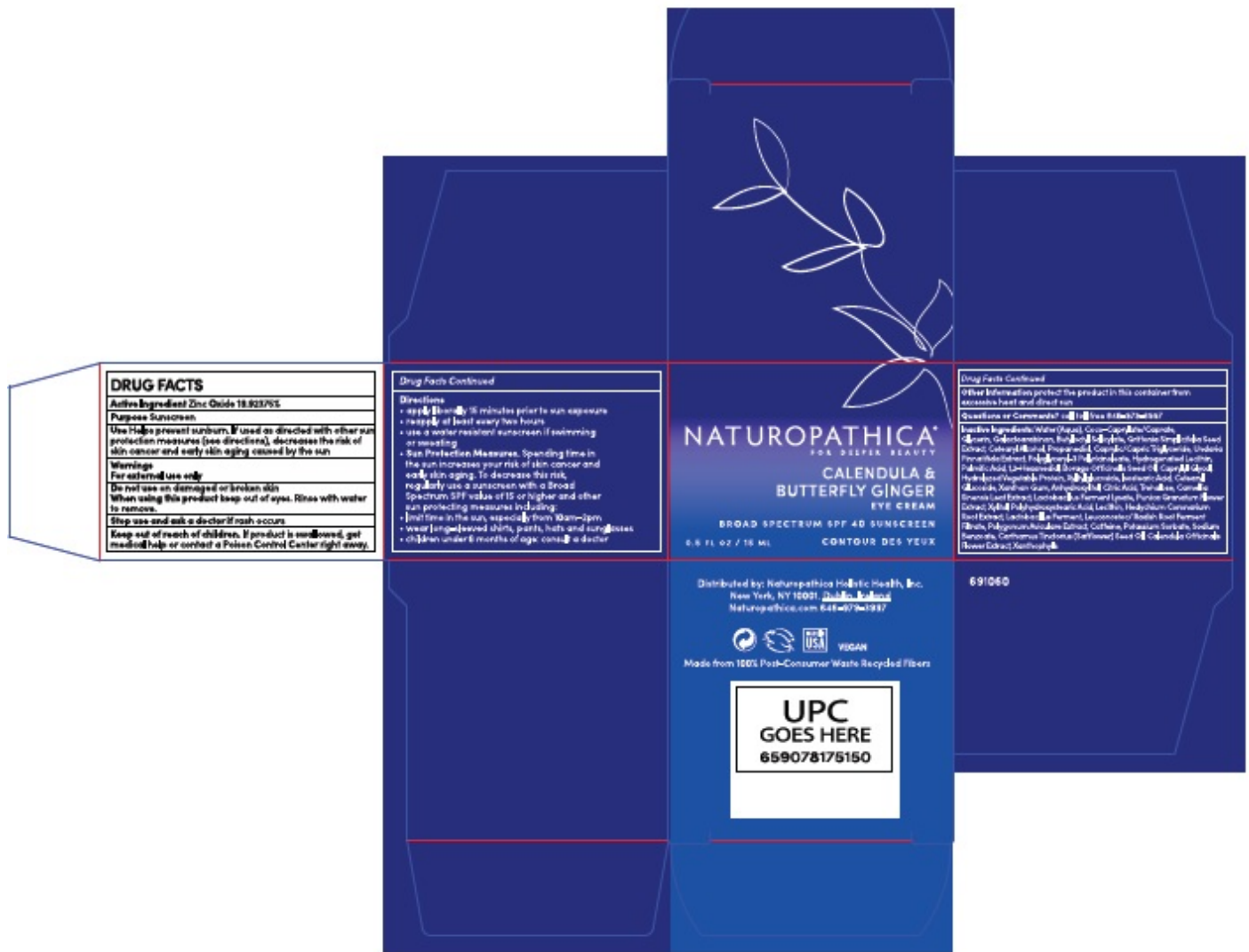
**HYDRATANT**

**0.5 FL OZ/50 ML**

**Distributed by: Naturopathica Holistic Health, Inc.**

**New York, NY 10001. Dublin, Ireland**

**Naturopathica.com 646-979-3997**



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NATUROPATHICA CALENDULA AND BUTTERFLY GINGER SPF 40 zinc oxide cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54111-153
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	19.92375 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
GLYCERIN (UNII: PDC6A3C0OX)	
GALACTOARABINAN (UNII: SL4SX1O487)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GRIFFONIA SIMPLICIFOLIA SEED (UNII: LUS5142TMY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PROPANEDIOL (UNII: 5965N8W85T)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
UNDARIA PINNATIFIDA (UNII: ICV1OK7M1S)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
PALMITIC ACID (UNII: 2V16EO95HI)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
BORAGE SEED OIL (UNII: F8XAG1755S)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
XYLITYLGLUCOSIDE (UNII: O0IEZ166FB)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROXYLITOL (UNII: 8XWR7NN42F)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
TREHALOSE (UNII: B8WCK70T7I)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
PUNICA GRANATUM FLOWER (UNII: D9B634V4GP)	
XYLITOL (UNII: VCQ006KQ1E)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
HEDYCHIUM CORONARIUM ROOT (UNII: 92A6N0IQN9)	
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
CAFFEINE (UNII: 3G6A5W338E)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
LUTEIN (UNII: X72A60C9MT)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54111-153-50	1 in 1 CARTON	01/31/2021	
1		15 mL in 1 JAR; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
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)

Revised: 2/2021

Bentley Laboratories, LLC