

ANNMARIE SPF 20 SUNSCREEN- zinc oxide 15% lotion
Annmari Gianni Skin Care 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.

Active Ingredients

Zinc Oxide 15%

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 eyes 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:

- after 80 minutes of swimming or sweating
- immediately after towel drying
- 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 risk, regularly use a sunscreen with broad spectrum SPF value of 15 or higher and other sun protection measure including:

- limit time in the sun, especially from 10 am to 2 pm
- wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: ask a doctor.

Inactive Ingredients

Helianthus Annuus (Sunflower) Seed Oil*, Sorbitan Olivatate, Cannabis Sativa Seed Oil*, Olea Europaea (Olive) Fruit Oil*, Cucurbita Pepo (Pumpkin) Seed Oil*, Beeswax*, Lavandula Angustifolia (Lavender) Oil, Persea Gratissima (Avocado) Oil*, Mauritia Flexuosa Fruit Oil, Tocopherol. *Organic

Label

<p>Drug Facts</p> <p>Active Ingredient Purpose</p> <p>Non-Nano Zinc Oxide 15%.....Sunscreen</p>	<p>Drug Facts (continued)</p> <p>Inactive ingredients</p> <p>*Helianthus annuus (sunflower) seed oil, Sorbitan olivate (olive derived emulsifier), *Cannabis sativa (hemp) seed oil, *Olea europaea (olive) fruit oil, *Cucurbita pepo (pumpkin) seed oil, *Cera alba (beeswax), Lavandula angustifolia (lavender) oil, *Persea gratissima (avocado) oil, Mauritia flexuosa (buriti) fruit oil, Tocopherol (non-GMO vitamin E). *Organically grown or wildcrafted</p>	 <p>SUN LOVE</p> <p>Everyday Sheer Sunscreen BROAD SPECTRUM SPF 20</p> <hr/> <p>All Skin Types</p> <hr/> <p>ANTIOXIDANT-RICH REEF FRIENDLY PARABEN FREE HYPOALLERGENIC</p> <p>1.7 fl oz / 50 mL</p>	<p>for all skin types. protects. moisturizes.</p> <p>Formulated with non-nano zinc oxide, this lightweight daily sunscreen protects the skin from UV rays, while adding deep moisturization. Infuse your skin with antioxidant-rich buriti fruit, pumpkin seed and hemp seed oil to nourish and visibly enhance your glow.</p> <p>FOR BEST RESULTS Shake thoroughly before each use. Apply AM after moisturizer. Reapply every 2 hours. Use a water resistant sunscreen if swimming or sweating. Recommended for face; also suitable for all over body application.</p>
<p>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.</p>			
<p>Warnings</p> <p>For external use only.</p> <p>Do not use on damaged or broken skin.</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash or irritation develops and lasts.</p> <p>Keep out of the reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p>			
<p>Directions • Apply liberally 15 minutes before sun exposure and as needed. 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 • For children under 6 months of age: ask a doctor.</p>	<p>WILD. BEAUTIFUL.</p> <p>MADE SAFE  </p> <p>Founded in Berkeley Annmarie Skin Care Hawleyville, CT 06440 (866) 729-9434 annmariegianni.com</p>		
<p>Other information • Protect the product in this container from excessive heat and direct sun • May stain fabrics.</p>			

ANNMARIE SPF 20 SUNSCREEN

zinc oxide 15% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82052-157
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PUMPKIN SEED OIL (UNII: 6E5QR5USSP)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
MAURITIA FLEXUOSA FRUIT OIL (UNII: 48H19MS04L)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82052-157-01	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/20/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/20/2021	

Labeler - Anmarie Gianni Skin Care LLC (050591758)

Registrant - Derma Care Research Labs, LLC (116817470)

Revised: 1/2023

Anmarie Gianni Skin Care LLC