NORWEX NATURAL SUNSCREEN BROAD SPECTRUM SPF 30- zinc oxide ointment Cosmetic Solutions 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.

Norwex® Natural Sunscreen Broad Spectrum SPF 30

DIRECTIONS

Apply liberally 15 minutes before sun exposure. Reapply at least every 2 hours or after 80 minutes of swimming or sweating and immediately after towel drying. For use on children under 6 months of age, consult 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 broad spectrum SPF 15 or higher, limit time in the sun (especially from 10 a.m.-2 p.m.), and wear long-sleeved shirts, pants, hats, and sunglasses.

WARNINGS

For external use only. Do not use on damaged/broken skin or if allergic to any of the ingredients. When using this product avoid contact with eyes. If contact occurs, rinse throughly with water. Stop use and consult a doctor if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Store at 15-30C. Do not use if safety seal is broken. May stain some fabrics.

MEDICINAL INGREDIENT MEDICINAL % W/W- P/P

Zinc Oxide 20%

NON-MEDICINAL INGREDIENTS

Helianthus Annuus (Sunflower) Seed Oil, Cera Alba (Beeswax), Ricinus Communis (Castor) Seed Oil, Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Butyrospermum Parkii (Shea) Butter, Tocopherols.

MANUFACTURED BY: PLS (Taos, New Mexico, USA) | DISTRIBUTED BY: Norwex Canada, Inc., Dauphin, MB R7N 3B3

PRINCIPAL DISPLAY PANEL - 85 g Tube Label

NATURAL SUNSCREEN EVERYDAY Broad Spectrum SPF 30 (UVA/UVB) Water Resistant (80 min) Non-Nano Dermatologist Tested

Norwex[®]

NPN 80091604

85 g / 3 oz. NET



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MODE D'EMPLOI: Appliquez librement 15 minutes avant l'exposition au soleil. Réappliquez toutes les 2 heures au moins ou après 80 minutes de baignade ou de transpiration et immédiatement après séchage à la serviette. Pour les enfants de moins de 6 mois, consultez un médecin. Mesures pour la protection solaire : Passer du temps au soleil augmente les risques de cancer de la peau et de vieillissement prématuré de la peau. Pour diminuer ce risque, utilisez régulièrement un écran solaire FPS 15 à large spectre ou supérieur, limitez le temps d'exposition au soleil (surtout entre 10 h et 14 h), et portez des chandails à manches longues, pantalons, chapeaux et lunettes de soleil. ATTENTION: Pour un usage externe seulement. Ne pas utiliser sur la peau blessée/abîmée ou en cas d'allergie aux ingrédients. En utilisant ce produit, évitez tout contact avec les yeux. En cas de contact, rincez abondamment à l'eau. En cas d'irritation, arrêtez l'utilisation et consultez un médecin. Gardez hors de portée des enfants. Si ingéré, contactez un centre antipoison ou consultez un médecin immédiatement. Entreposez entre 15 et 30oC. Ne pas utiliser si le sceau de sécurité est brisé. Pourrait tacher certains tissus.

MEDICINAL INGREDIENT MEDICINAL % W/W- P/P: Zinc Oxide/ Oxyde de zinc (20%) NON-MEDICINAL INGREDIENTS NON MEDICINAUX: Helianthus Annuus (Sunflower) Seed Oil, Cera Alba (Beeswax), Ricinus Communis (Castor) Seed Oil, Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Butyrospermum Parkii (Shea) Butter, Tocopherols.

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zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66163-1000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	20 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
CASTOR OIL (UNII: D5340Y2I9G)		
JOJOBA OIL (UNII: 724GKU717M)		
TOCOPHEROL (UNII: ROZB2556P8)		
COCONUT OIL (UNII: Q9L0O73W7L)		
OLIVE OIL (UNII: 6UYK2WIWIE)		
SHEA BUTTER (UNII: K49155WL9Y)		
WHITE WAX (UNII: 7G1J5DA97F)		
SUNFLOWER OIL (UNII: 3W1JG795YI)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:66163- 1000-1	85 g in 1 TUBE; Type 0: Not a Combination Product	07/01/2019		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	07/01/2019		

Labeler - Cosmetic Solutions LLC (807907928)

Revised: 1/2023 Cosmetic Solutions LLC