BADGER SPF 34 ANTI-BUG SUNSCREEN- zinc oxide cream Norwood Packaging Ltd.

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.

Badger® SPF 34 Anti-Bug Sunscreen

Drug Facts

Active Sunscreen Ingredient

Non-Nano Uncoated Zinc Oxide 20%

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.

Caution

For external use only

Do not use on damaged or broken skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Stop and ask a doctor if rash occurs.

When using this product keep out of eyes. Rinse with water to remove.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

- Adult supervision required.
- Do not apply to children's hands.

Directions

• For full protection, apply liberally (2mg/cm² of skin) to all exposed skin 15 minutes before sun exposure, then rub in to reduce whitening effect.

Reapply

- After 40 minutes of swimming or sweating
- Immediately after towel drying
- At least every 2 hours

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 value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10am-2pm
 - Wear long-sleeved shirts, pants, hats, and sunglasses
- For children under 6 months of age: ask a doctor.

Ingredients

¹Olea Europaea (**Extra Virgin Olive**) Oil, ¹Cera Alba (**Beeswax**), ¹Ricinus Communis (**Castor**) Oil, ¹Cymbopogon Nardus (**Citronella**) Oil, ¹Cymbopogon Schoenanthus (**Lemongrass**) Oil, ¹Cedrus Deodara (**Cedar**) Oil, ¹Rosmarinus Officinalis (**Rosemary**) Oil, and ¹Pelargonium Graveolens (**Geranium**) Oil.

1 =Certified Organic

PRINCIPAL DISPLAY PANEL - 87 ml Tube Label

Active

BADGER_®

DEET

FREE

Citronella & Cedar

Broad Spectrum

SPF 34

ANTI-BUG

SUNSCREEN

Tested to Repel Mosquitoes Certified Natural • Contains 98% Organic Ingredients

WATER

RESISTANT

40 min

UVA

UVB

NON

NANO

BIO

DEGRADABLE

ACTIVE ANTI-BUG INGREDIENTS (15.5%): 10% *Castor Oil, & Essential Oils of 2.5% *Citronella, 1.25% *Lemongrass, 1% *Cedar, 0.5% *Rosemary, & 0.25% *Geranium.

OTHER INGREDIENTS (84.5%): *Extra Virgin Olive Oil, Zinc Oxide, *Beeswax. *= Certified Organic

87ml/2.9 fl.oz



BADGER SPF 34 ANTI-BUG SUNSCREEN

zinc oxide cream

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55143-103 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 mL	

Inactive Ingredients	
Ingredient Name	Strength
OLIVE OIL (UNII: 6 UYK2W1W1E)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CASTOR OIL (UNII: D5340 Y2I9G)	
CITRO NELLA O IL (UNII: QYO8Q067D0)	
CEDRUS DEODARA WOOD (UNII: 1GO876QOY2)	
ROSEMARY OIL (UNII: 8LGU7VM393)	

WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED))
GERANIUM O.IL. ALGERIAN TYPE (UNII: 501194P4WG)

Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:55143-103-01	87 mL in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	0 1/0 1/20 14	

Labeler - Norwood Packaging Ltd. (243693926)

Establishment				
Name	Address	ID/FEI	Business Operations	
Norwood Packaging Ltd.		243693926	MANUFACTURE(55143-103)	

Revised: 1/2014 Norwood Packaging Ltd.