

BADGER UNSCENTED SPF 30 SUNSCREEN- zinc oxide cream
Twincraft Inc

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® Unscented SPF 30 Sunscreen Cream

PRINCIPAL DISPLAY PANEL - 87 ml Tube Label

Active Ingredient	Purpose
Non-Nano Uncoated Zinc Oxide 18.75%	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. Stop use 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 product is swallowed, get medical help or contact a Poison Control Center right away.

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 a 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 *Helianthus Annuus (Sunflower) Seed Oil, *Cera Alba (Beeswax), Tocopherol (Sunflower Vitamin E), *Hippophae Rhamnoides (Seabuckthorn) Fruit Extract. * = Certified Organic

Other Information: Store at temperatures below 90°F.

BADGER UNSCENTED SPF 30 SUNSCREEN			
zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64412-4740

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	18.75 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795Y)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
TOCOPHEROL (UNII: R0ZB2556P8)	
HIPPO PHAE RHAMNOIDES FRUIT (UNII: AVL0R9111T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64412-4740-0	87 mL in 1 TUBE; Type 0: Not a Combination Product	12/15/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/15/2015	

Labeler - Twincraft Inc (093248870)