# BADGER SPF30 UNSCENTED SUNSCREEN UNSCENTED- zinc oxide ointment Autumn Harp, 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.

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#### **Drug Facts**

#### **Active Ungredient**

Non-Nano Uncoated Zinc Oxide 18.75%

#### Purpose

Sunscreen

#### Uses:

- Helps prevent sunburn
- Reatins SPF after 40 minutes of activity in the water or perspiring
- Higher SPF gives more sunburn protection

#### Warnings:

For external use only

#### When using this product

Keep out of eyes. Rinse with water to remove

#### Stop use and ask a doctor if

Rash pr irritation develops and lasts

#### Directions:

- For full protection, apply ample white coat to all exposed skin, then rub to reduce the whitening effect.
- Some separation may occur. Knead tube before use.
- Reapply after swimming and sweating as needed.
- For children under 6 months of age: ask a doctor



### **BADGER SPF30 UNSCENTED SUNSCREEN UNSCENTED**

zinc oxide ointment

Product Information								
Product T ype	HUMAN OTC DRUG	Item Code (Source) ND		C:51514-201				
Route of Administration	TOPICAL							
Active Ingredient/Active Moiety								
Ingredient Name			<b>Basis of Strength</b>		Strength			
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)			Zinc Oxide 1		18.75 mL in 100 mL			
Inactive Ingredients								
Ingredient Name					Strength			
OLIVE OIL (UNII: 6 UYK2W1W1E)								
YELLOW WAX (UNII: 2ZA36H0S2V)								

SHEA BUTTER (UNII: K49	155WL9Y)							
COCOA BUTTER (UNII: 5120 YT1CRR)								
JO JOBA OIL (UNII: 724GKU717M)								
TOCOPHEROL (UNII: R0ZB2556P8)								
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)								
Packaging								
# Item Code	Package Description	Marketing Start Date M		Mar	arketing End Date			
1 NDC:51514-201-01	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		11/10/2011					

# Labeler - Autumn Harp, Inc. (064187883)

## Establishment

Name	Address	ID/FEI	Business Operations
Autumn Harp, Inc.		064187883	manufacture

Revised: 11/2011

Autumn Harp, Inc.