

## **BOOTY GOO - zinc oxide ointment**

**Skin Sake, 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.*

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### **Active Ingredient**

#### **Drug Facts**

#### **Active Ingredient**

Zinc Oxide 25%

#### **Purpose**

Skin Protectant

#### **Keep out of reach of children**

**Keep out of reach of children.**

#### **Uses**

- Helps soothe, treat , and prevent diaper rash
- Repels wetness
- Protects delicate skin
- Relieves chapped, moist or irritated areas
- Prevents Friction

#### **Warnings**

**For external use only.**

**When using this product,** do not get into eyes.

**Stop and ask a doctor if** condition worsens, symptoms last more than 7 days or clear up and occur again within a few days.

**Do not use on** deep puncture wounds, animal bites, serious burns.

**If swallowed,** get medical help or contact a Poison control Center right away.

#### **Directions**

Cleanse and dry diaper area. Apply liberally as often as necessary, with each diaper change at least 3 or 4 times a day, definitely at bedtime when wet diapers may be prolonged. Store between 15° - 30° C, (59° - 86° F)

#### **Inactive ingredients**

Peruvian Balsam, Vitamin E (Tocopherol), Aloe, Acidum Boricum, White Petrolatum, Mineral Oil, Castor Oil, Microcrystalline Wax, White Beeswax.

**Product Label**

**NDC # 434479440-1**

**Pharmacist Formulated Pediatrician Recommended**

**Booty®Goo**

**DIAPER CHANGE OINTMENT**

**Soothes, treats and prevents Diaper Rash**

FrAGRANCE Free

Repels Wetness

Natural Ingredients for Healthy Skin

Non-Greasey, Non-Staining

Net Wt 2.5 oz (71g)

VISIBLE IMPROVEMENT WITHIN 24 HRS

Manufactured by:

**SKIN SAKE, LLC**

P.O. Box 390, Hamburg, AT 71646

1-888-853-5544 [bootygoo.com](http://bootygoo.com)

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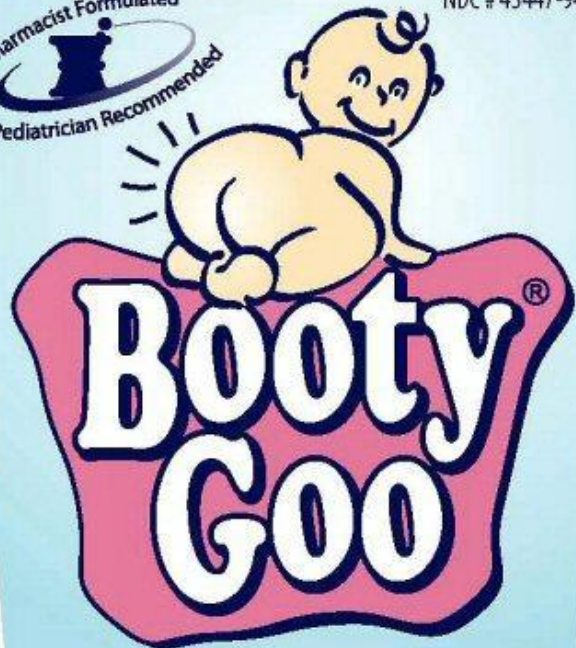
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Pharmacist Formulated  
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## DIAPER CHANGE OINTMENT

*Soothes, Treats and  
Prevents Diaper Rash*

- ◆ Fragrance Free
- ◆ Repels Wetness
- ◆ Natural Ingredients  
for Healthy Skin
- ◆ Non-Greasy, Non-Staining

Net Wt 2.5 oz. (71 g)

**BOOTY GOO**

zinc oxide ointment

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43447-9440
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	17.75 g in 71 g

**Inactive Ingredients**

Ingredient Name	Strength
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<b>BALSAM PERU</b> (UNII: 8P5F881OCY)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>ALOE</b> (UNII: V5VD430YW9)	
<b>BORIC ACID</b> (UNII: R57ZHV85D4)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43447-9440-1	71 g in 1 TUBE		
2	NDC:43447-9440-0	100 in 1 BOX		
2	NDC:43447-9440-2	2 g in 1 PACKET		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	12/01/2005	

**Labeler** - Skin Sake, LLC (195912717)

**Registrant** - Skin Sake, LLC (195912717)

### Establishment

Name	Address	ID/FEI	Business Operations
Memphis Contract Packaging, Inc.		185390010	manufacture(43447-9440)