# BABY BUTZ- zinc oxide cream Olen Cosmetics Corporation

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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# **Baby Butz**

# **Active Ingredients**

Zinc Oxide 30%

### **Purpose**

Skin Protectant

#### Use

- Helps treat and prevent diaper rash
- Protects chafed skin due to diaper rash
- Helps seal out wetness

# Warnings

# For External Use Only

If condition worsen or does not improve within 7 days, consult a physician.

# When Using this Product

Avoid Contact with eyes.

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

#### **Directions**

Change wet or soiled diapers promptly. Cleanse the diaper area and allow to dry. Apply cream liberally as often as necessary with each diaper change especially at bedtime or any time exposure to wet diaper my be prolonged.

#### Other Information

Store between 15-30 degrees

#### **Inactive Ingredients**

corn starch, lanolin, petrolatum

#### Questions?

1-877-494-4313

# **Principal Display Panel**

Baby Butz

Cream

Relieves + Prevents

Diaper Rash

100% Natural

30% Zinc Oxide Cream

Earth-friendly

babybutz.com











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#### **BABY BUTZ**

zinc oxide cream

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:52358-0001

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name
Basis of Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)
ZINC OXIDE
17.1 g in 57 g

nactive Ingredients				
Ingredient Name	Strength			
STARCH, CORN (UNII: O8232NY3SJ)				
LANOLIN (UNII: 7EV65EAW6H)				
PETROLATUM (UNII: 4T6H12BN9U)				

# **Packaging**

#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:52358-0001-1	57 g in 1 JAR; Type 0: Not a Combination Product	11/02/2015	
2	NDC:52358-0001-2	113 g in 1 JAR; Type 0: Not a Combination Product	11/02/2015	
3	NDC:52358-0001-3	227 g in 1 JAR; Type 0: Not a Combination Product	06/12/2018	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part347	07/15/2013			

# Labeler - Olen Cosmetics Corporation (250916611)

Revised: 6/2018 Olen Cosmetics Corporation