

BABYS BUTT AID- zinc oxide ointment
GREENBRIER INTERNATIONAL 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.

DRUG FACTS

For external use only

- flammable, keep away from fire and flame
- will produce serious gastric disturbances if taken internally

Ask a doctor before use if you have deep puncture wounds or serious burns

When using this product

- do not get into eyes or mucous membranes
- use only in a well-ventilated area

Stop use and ask a doctor if condition persists or gets worse.

Keep out of reach of children. In case of an accidental ingestion, contact a Poison Control Center immediately.

Active ingredient

Zinc Oxide 16%

Purpose

Skin Protectant

Uses

- Helps treat and prevent diaper rash
- Prevents chafed skin due to diaper rash and helps seal out wetness.

Warnings

For external use only.

When using this product, avoid contact with eyes.

Stop use and ask a doctor if condition worsens or does not improve within 7 days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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

Other information

store at 20 to 27 C (68 to 80.6 F)

Inactive ingredients

boric acid, castor oil, microcrystalline wax, mineral oil, paraffin, peruvian balsam, petrolatum



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BABYS BUTT AID

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-1306
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	16 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	2 g in 100 g

CASTOR OIL (UNII: D5340Y2I9G)	30 g in 100 g
MINERAL OIL (UNII: T5L8T28FGP)	31.5 g in 100 g
PARAFFIN (UNII: I9O0E3H2ZE)	10 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U)	10 g in 100 g

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-1306-1	1 in 1 BOX		
1		56 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/01/2011	

Labeler - GREENBRIER INTERNATIONAL INC (610322518)

Registrant - HUZHOUMINO DAILY CHEMICALS COMPANY LIMITED (547695235)

Establishment

Name	Address	ID/FEI	Business Operations
HUZHOUMINO DAILY CHEMICALS COMPANY LIMITED		547695235	manufacture(33992-1306)

Revised: 1/2014

GREENBRIER INTERNATIONAL INC