

BABY BUM DIAPER RASH- zinc oxide cream
Sun Bum 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.

Baby Bum Diaper Rash Cream

Drug Facts

Active Ingredients

Zinc oxide 16%

Purpose

Skin protectant

Uses

- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash and helps seal out wetness

Warnings

For external use only

When using this product

do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again withing a few 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 area to dry
- apply cream liberally as often as necessary with each diaper change, especially at bedtime or any time exposure to wet diapers may be prolonged

Other Information

- store between 20° to 25°C (68° to 77°F)
- do not use if quality seal is broken

Inactive ingredients

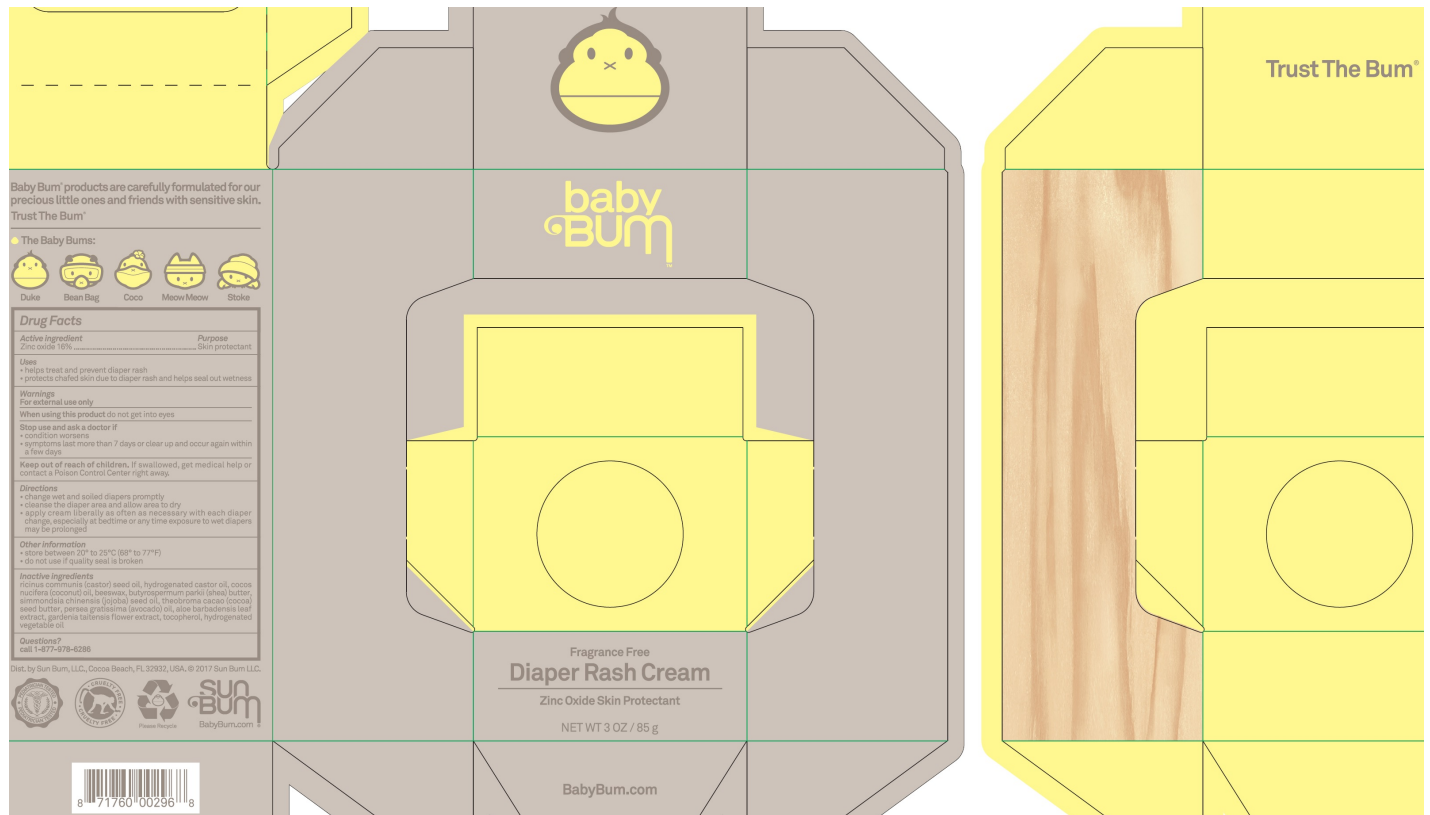
ricinus communis (castor) seed oil, hydrogenated castor oil, cocos nucifera (coconut) oil, beeswax,

butyrospermum parkii (shea) butter, simmondsia chinensis (jojoba) seed oil, theobroma cacao (cocoa) seed butter, persea gratissima (avocado) oil, aloe barbadensis leaf extract, gardenia taitensis flower extract, tocopherol, hydrogenated vegetable oil

Questions?

Call 1-877-978-6286

Package Labeling:



BABY BUM DIAPER RASH

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-279
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	160 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	

COCONUT OIL (UNII: Q9L0O73W7L)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SHEA BUTTER (UNII: K49155WL9Y)	
JOJOBA OIL (UNII: 724GKU717M)	
COCOA BUTTER (UNII: 512OYT1CRR)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GARDENIA TAITENSIS FLOWER (UNII: T0OCU8201Y)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-279-00	1 in 1 BOX	01/01/2018	
1		85 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/01/2018	

Labeler - Sun Bum LLC (028642574)