BABY DIAPER RASH- zinc oxide cream
Xtreme Tools 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.

BABY DIAPER RASH CREAM

Active ingredient

Zinc Oxide 17%

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 within a few day

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 cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Other Information

- Store at 20° to 25°C (68° to 77°F)
- May stain clothing

Inactive ingredients

Water (Aqua), Vegetable Oil (Olus Oil in the EU), Butyrospermum parkii (Shea Butter) Fruit, Cocos Nucifera (Coconut) Oil, Glycerin, Vitis Vinifera (Grape) Seed Oil, Aloe Barbadensis Leaf Extract, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Lavandula Angusfifolia (Lavender) Oil, Simmondsia

Chinensis (Jojoba) Seed Oil, Anthemis Nobilis Flower extract, Shea Butter Ethyl Esters, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Hydrogenated Vegetable Oil, Heptyl Undecylenate, Polyglyceryl-2 Dipolyhydroxystearate, Cetearyl Alcohol, Polisorbate 60, Myrica Pubescens Fruit wax, Beeswax, Tocopheryl Acetate, Panthenol, Phenoxyethanol, Ethylhexylglycerin, Citric Acid

Questions or comments?

Call 1-305-622-7474, Monday through Friday 9:00 AM to 5:00 PM

Principal Display Panel

198 g in Jar; NDC 74553-002-01

BABY DIAPER RASH

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74553-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	17 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
HEPTYL UNDECYLENATE (UNII: W77QUB6GXO)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
JOJOBA OIL (UNII: 724GKU717M)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALMOND OIL (UNII: 66YXD4DKO9)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
SHEA BUTTER (UNII: K49155WL9Y)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
GLYCERIN (UNII: PDC6A3C0OX)	

GRAPE SEED OIL (UNII: 930MLC8XGG)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
MORELLA PUBESCENS FRUIT WAX (UNII: 2N43GS24LV)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
PANTHENOL (UNII: WV9CM0O67Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCONUT OIL (UNII: Q9L0O73W7L)	
SHEA BUTTER ETHYL ESTERS (UNII: V2CI786FPG)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74553-002-01	198 g in 1 JAR; Type 0: Not a Combination Product	10/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/06/2020	

Labeler - Xtreme Tools International, Inc (125398904)

Registrant - Xtreme Tools International, Inc (125398904)

Establishment

Name	Address	ID/FEI	Business Operations
Xtreme Tools International, Inc		125398904	manufacture(74553-002)

Revised: 10/2020 Xtreme Tools International, Inc