DIAPER RASH CREAM- zinc oxide cream Hamilton Therapeutics, 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.

Diaper Rash Cream

Active ingredient Purpose

Zinc Oxide 15% Skin Protectant

Uses Helps treat and prevent diaper rash. Protects chafed skin due to diaper rash and helps seal out wetness.

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

Stop use and ask adoctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days.

WarningsFor external use only.

When using this product • Avoid contact with eyes

Directions

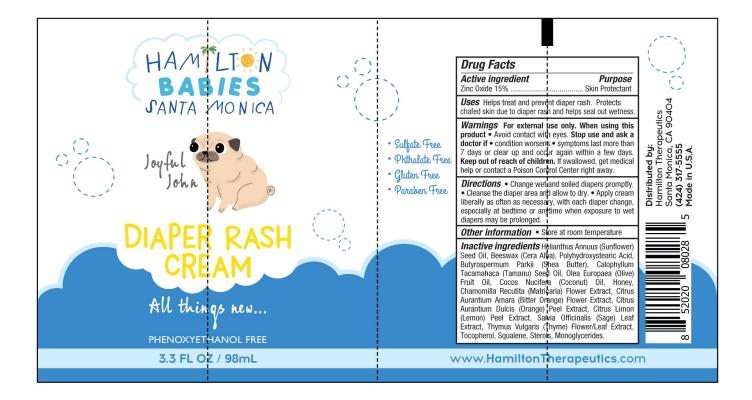
- Change wet and soiled diapers promptly.
- Cleanse the diaper area and allow to dry. Apply cream liberally as often as necessary, with each diaper change,

especially at bedtime or anytime when exposure to wet diapers may be prolonged.

Inactive ingredients Helianthus Annuus (Sunflower) Seed Oil, Beeswax (Cera Alba), Polyhydroxystearic Acid, Butyrospermum Parkii (Shea Butter), Calophyllum Tacamahaca (Tamanu) Seed Oil, Olea Europaea (Olive) Fruit Oil, Cocos Nucifera (Coconut) Oil, Honey, Chamomilla Recutita (Matricaria) Flower Extract, Citrus Aurantium Amara (Bitter Orange) Flower Extract, Citrus Aurantium Dulcis (Orange) Peel Extract, Citrus Limon (Lemon) Peel Extract, Salvia Officinalis (Sage) Leaf Extract, Thymus Vulgaris (Thyme) Flower/Leaf Extract,Tocopherol, Squalene, Sterols, Monoglycerides.

Diaper Rash Cream

3.3 FL OZ / 98mL



zinc oxide cream						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source) ND		NDC:72381-101	DC:72381-101	
Route of Administration	TOPICAL					
Active Ingredient/Active	Moiety					
Ingred	ient Name		Basis of Streng	yth Streng	th	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC				15 g in 100) mL	
Inactive Ingradiants						
Inactive Ingredients				-		
	Ingredient Name			Streng	th	
SUNFLOWER OIL (UNII: 3W1JG795	YI)			Streng	th	
SUNFLOWER OIL (UNII: 3W1JG795 POLYHYDROXYSTEARIC ACID (2	YI) 300 MW) (UNII: YXH47AOU	IOF)		Streng	th	
SUNFLOWER OIL (UNII: 3W1JG795 POLYHYDROXYSTEARIC ACID (2 SHEA BUTTER (UNII: K49155WL9Y	YI) 300 MW) (UNII: YXH47AOU)	IOF)		Streng	th	
SUNFLOWER OIL (UNII: 3W1JG795 POLYHYDROXYSTEARIC ACID (2 SHEA BUTTER (UNII: K49155WL9Y COCONUT OIL (UNII: Q9L0073W7)	YI) 300 MW) (UNII: YXH47AOU) _)	- -		Streng	th	
SUNFLOWER OIL (UNII: 3W1JG795 POLYHYDROXYSTEARIC ACID (2 SHEA BUTTER (UNII: K49155WL9Y COCONUT OIL (UNII: Q9L0073W7 CALOPHYLLUM TACAMAHACA SI	YI) 300 MW) (UNII: YXH47AOU) _)	- -		Streng	th	
SUNFLOWER OIL (UNII: 3W1JG795 POLYHYDROXYSTEARIC ACID (2 SHEA BUTTER (UNII: K49155WL9Y COCONUT OIL (UNII: Q9L0073W7) CALOPHYLLUM TACAMAHACA SI OLIVE OIL (UNII: 6UYK2W1W1E)	YI) 300 MW) (UNII: YXH47AOU) _)	- -		Streng	th	
SUNFLOWER OIL (UNII: 3W1JG795 POLYHYDROXYSTEARIC ACID (2 SHEA BUTTER (UNII: K49155WL9Y COCONUT OIL (UNII: Q9L0073W7I CALOPHYLLUM TACAMAHACA SI OLIVE OIL (UNII: 6UYK2W1W1E) HONEY (UNII: Y9H1V576FH)	YI) 300 MW) (UNII: YXH47AOU) _)	- -		Streng	th	
SUNFLOWER OIL (UNII: 3W1JG795 POLYHYDROXYSTEARIC ACID (2 SHEA BUTTER (UNII: K49155WL9Y COCONUT OIL (UNII: Q9L0073W7) CALOPHYLLUM TACAMAHACA SI OLIVE OIL (UNII: 6UYK2W1W1E) HONEY (UNII: Y9H1V576FH) LEMON PEEL (UNII: 720054U628)	YI) 300 MW) (UNII: YXH47AOU) _)	- -		Streng	th	
SUNFLOWER OIL (UNII: 3W1JG795 POLYHYDROXYSTEARIC ACID (2 SHEA BUTTER (UNII: K49155WL9Y COCONUT OIL (UNII: Q9L0073W7) CALOPHYLLUM TACAMAHACA SI OLIVE OIL (UNII: 6UYK2W1W1E) HONEY (UNII: Y9H1V576FH) LEMON PEEL (UNII: 720054U628) SAGE (UNII: 065C5D077J)	YI) 300 MW) (UNII: YXH47AOU) _)	- -		Streng	th	
SUNFLOWER OIL (UNII: 3WIJG795 POLYHYDROXYSTEARIC ACID (2 SHEA BUTTER (UNII: K49155WL9Y COCONUT OIL (UNII: Q9L0073W7) CALOPHYLLUM TACAMAHACA SI OLIVE OIL (UNII: 6UYK2W1W1E) HONEY (UNII: Y9H1V576FH) LEMON PEEL (UNII: 720054U628)	YI) 300 MW) (UNII: YXH47AOU) _)	- -		Streng	th	

С⊦	IAMOMILE (UNII: F	GL3685T2X)							
CITRUS AURANTIUM FLOWER (UNII: 0730ZX2Z83)									
CITRUS SINENSIS FLOWER (UNII: H02N5LQ5F6)									
THYME (UNII: CW657OBU4N)									
TOCOPHEROL (UNII: R0ZB2556P8)									
Packaging									
#	ltem Code	Package Description	I	Marketing Start Date	Ma	arketing End Date			
1		98 mL in 1 TUBE; Type 0: Not a Combination Product	06,	/07/2018					
Marketing Information									
	Marketing Category	Application Number or Monograph Citation		Marketing Start Date	M	larketing End Date			
ОТ	C monograph final	part347		06/07/2018					

Labeler - Hamilton Therapeutics, Inc (099419360)

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Hamilton Therapeutics, Inc