BABY ECZEMA MOISTURIZING- colloidal oatmeal cream Harmon Stores 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.

buybuy Baby™ Eczema Moisturizing Cream

Active ingredient

Colloidal Oatmeal 1%

Purpose

Skin Protectant

Uses

Temporarily protects and helps relieve minor skin irritation and itching due to:

- Eczema
- Rashes

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 days.

Keep Out of Reach of Children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

apply as needed

Inactive ingredients

water, glycerin, distearyldimonium chloride, isopropyl palmitate, cetearyl alcohol, petrolatum, avena sativa (oat) kernel flour, dimethicone, steareth-21, panthenol (pro-vitamin B5), benzalkonium chloride, sodium chloride, ceramide 3, ceramide 6-II, ceramide 1, phytosphingosine, cholesterol, sodium lauroyl lactylate, carbomer, xanthan gum, sativa (oat) kernel oil, avena sativa (oat) kernel extract, triethanolamine.

Package/Label Principal Display Panel

buybuy BABY™ eczema MOISTURIZING CREAM

colloidal oatmeal skin protectant

Helps relieve dry, itchy and irritated skin

Helps sooth eczema related skin conditions

Steroid-free

Fragrance-free

DERMATOLOGIST TESTED

NET WT 5 OZ (140 g)

baby eczema moisturizing cream

Enriched with soothing oatmeal, this innovative cream offers relief to help care for dry, itchy skin, while intensely moisturizing it. It helps to fortify your baby's skin's natural barrier functions while helping to prevent the recurrence of dry skin. Our formula is enriched with ceramides, essential lipids naturally found in the skin, to enhance and restore the baby's skin's natural protective function.

MADE EXPRESSLY FOR **buybuy** BABY[™] 650 Liberty Avenue, Union, NJ 07083 © BUY BUY BABY INC. WWW.BUYBUYBABY.COM MADE IN ISRAEL



Container Label

BABY ECZEMA MOISTURIZING colloidal oatmeal cream **Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:63940-429 **Route of Administration** TOPICAL Active Ingredient/Active Moiety **Ingredient Name Basis of Strength** Strength OATMEAL (UNII: 8 PI54V663Y) (OATMEAL - UNII:8 PI54V663Y) OATMEAL 1 g in 100 g **Inactive Ingredients Ingredient Name** Strength WATER (UNII: 059QF0KO0R)

GLYCERIN (UNII: PDC6A3C0OX)

DISTEARYLDIMO NIUM CHLO RIDE (UNII: OM9573ZX3X)	
ISOPROPYL PALMITATE (UNII: 8 CRQ2TH63M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128 M1S)	
PETROLATUM (UNII: 4T6H12BN9U)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
STEARETH-21 (UNII: 53J3F32P58)	
PANTHENOL (UNII: WV9CM0O67Z)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CERAMIDE 3 (UNII: 4370 DF0 50 B)	
CERAMIDE 6 II (UNII: F1X8L2B00J)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
PHYTOSPHINGOSINE (UNII: GIN46 U9 Q2Q)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SODIUM LAURO YL LACTYLATE (UNII: 7243K85WFO)	
XANTHAN GUM (UNII: TTV12P4NEE)	
OAT KERNEL OIL (UNII: 3UVP41R77R)	
OAT (UNII: Z6J799EAJK)	
TROLAMINE (UNII: 903K93S3TK)	

	Packaging							
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
l	1	NDC:63940-429-12	140 g in 1 TUBE; Type 0: Not a Combination Product					

Marketing Info	arketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part347	09/01/2014					

Labeler - Harmon Stores Inc. (804085293)

Revised: 9/2014 Harmon Stores Inc.