GRANDMA ELS- diaper rash ointment ointment MEADOWBROOK LABS, 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:

NDC #52248-200-41

Active Ingredients

Amber Petroluatum 75.95%..... Lanolin 15.50%.....

Purpose

......Protectant, EmollientProtectant, Emollient

Uses: Helps treat and prevent diaper rash • Protects and heals chafed and irritated skin • Provides barrier to seal out wetness • Helps alleviate pain, itching and redness associated with diaper rash

Warnings: For external use only

When using this product • do not get into eyes

Stop use and ask a doctor if • condition worsens • symtoms last more than 7 day or clear up and occur again within a few days

Do not use on • deep or puncture wounds • animal bites • serious burns

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

Directions: Change wet and soiled diapers promptly. Cleanse diaper area and allow to dry. Apply a thin film of ointment to entire diaper area with every diaper change.

Other Information: Store at 20° to 25°C (68° to 77°F) May stain clothing

Other Ingredients:

Tocopherol Acetate (Vitamin E), Cetyl Esters, Ethyl Methylphenylglycidate, Benzly Cinnamate (extracts of balsam of peru)

For Questions call (800) 493-0223 Mon-Fri

Works with most cloth diapers please contact your diaper manufacturer Mfd for Meadowbrook Labs, Inc., Farmingdale, NY

DOES NOT CONTAIN PARABENS, PHTHALATES, OR SLS.

www.GrandmaEls.com

———PACKAGE LABEL.PRINCIPAL DISPLY PANEL———

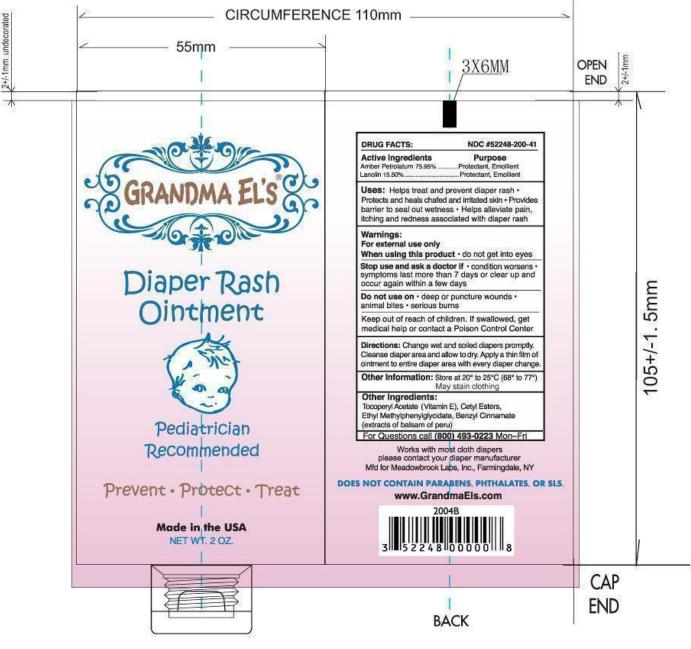
GRANDMA EL'S

Diaper Rash Ointment

Pediatrician Recommended

Prevent • Protect • Treat

Made in the USA NET WT. 2 OZ



FRONT

GRANDMA ELS									
diaper rash ointment ointment									
Product Information									
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52248-200						
Route of Administration	TOPICAL								

		Ingredient Name		Basis of Streng	gth	Strength	
РЕТ	PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) PETROLATUM					0.7595 g in 1 g	
LAN	LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H) LANOLIN					0.155 g in 1 g	
Ina	ctive Ingredie	nts					
		Ingredient Name				Strength	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)							
CETYL ESTERS WAX (UNII: D072FFP9GU)							
ETHYL METHYLPHENYLGLYCIDATE (UNII: UD51D5KR4A)							
BENZYL CINNAMATE (UNII: V67O3RO97U)							
BEN		. ,					
		. ,					
Pac	ZYL CINNAMATE	. ,	Market	ing Start Date	Mark	eting End Dat	
Pac #	IZYL CINNAMATE	(UNII: V6703R097U) Package Description	Market	ing Start Date	Mark	eting End Dat	
Pac # 1 N	izyl CINNAMATE ckaging Item Code	(UNII: V6703R097U) Package Description	Market	ing Start Date	Mark	eting End Dat	
Pac # 1 N 2 N	EXAG IND Chag Ing Item Code DC:52248-200-41 DC:52248-200-42	E (UNII: V6703R097U) Package Description 56.7 g in 1 TUBE; Type 0: Not a Combination Product	Market	ing Start Date	Mark	eting End Dat	
Pac # 1 N 2 N	EXAG IND Chag Ing Item Code DC:52248-200-41 DC:52248-200-42	E (UNII: V67O3RO97U) Package Description 56.7 g in 1 TUBE; Type 0: Not a Combination Product 106.3 g in 1 JAR; Type 0: Not a Combination Product	Market	ing Start Date	Mark	eting End Dat	
Pac # 1 N 2 N	EXAG IND Chag Ing Item Code DC:52248-200-41 DC:52248-200-42	E (UNII: V67O3RO97U) Package Description 56.7 g in 1 TUBE; Type 0: Not a Combination Product 106.3 g in 1 JAR; Type 0: Not a Combination Product	Market	ing Start Date	Mark	eting End Dat	
Pac # 1 N1 2 N1 3 N1	EXAG IND Chag Ing Item Code DC:52248-200-41 DC:52248-200-42	E (UNII: V67O3RO97U) Package Description 56.7 g in 1 TUBE; Type 0: Not a Combination Product 106.3 g in 1 JAR; Type 0: Not a Combination Product 1.75 g in 1 TUBE; Type 0: Not a Combination Product	Market	ing Start Date	Mark	eting End Dat	
Pac # 1 N 2 N 3 N	Exaging Item Code DC:52248-200-41 DC:52248-200-42 DC:52248-200-43	E (UNII: V67O3RO97U) Package Description 56.7 g in 1 TUBE; Type 0: Not a Combination Product 106.3 g in 1 JAR; Type 0: Not a Combination Product 1.75 g in 1 TUBE; Type 0: Not a Combination Product Drmation		ting Start Date		eting End Dat	

Labeler - MEADOWBROOK LABS, INC. (799274183)

Establishment

Name	Address	ID/FEI	Business Operations
ABBE Laboratories, Inc.		781745286	manufacture(52248-200)

Revised: 12/2014

MEADOWBROOK LABS, INC.