

GRANDMA ELS- diaper rash ointment ointment
ABBE Laboratories, 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.

Active Ingredients

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

Purpose

.....Protectant, Emollient
.....Protectant, Emollient

Uses: Helps treat and prevent diaper rash • Protects and heals chafed and irritated skin
• Provides barrier to 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 • 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)

Other Ingredients:

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

For Questions call **(800) 457-0990** Mon-Fri

Mfd. by ABBE Laboratories, Inc. Farmingdale, NY

www.GrandmaEls.com

——PACKAGE LABEL.PRINCIPAL DISPLY PANEL——

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wwwGrandmaEls.com

Creates a

Breathable Barrier

Use with Every

Diaper Change

Soothes, Calms

+ Heals

NET WT 3.75 OZ.

GRANDMA EL'S

Diaper Rash Ointment

Made in the USA

Pediatrician Recommended

DOES NOT CONTAIN

PARABENS,

PHTHALATES OR SLS

DRUG FACTS:

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Lanolin USP 15.50%.....Protectant, Emollient

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GRANDMA ELS

diaper rash ointment ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68605-2007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	0.7595 g in 1 g
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	0.155 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
ETHYL METHYLPHENYLGLYCIDATE (UNII: UD51D5KR4A)	
BENZYL CINNAMATE (UNII: V67O3RO97U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:68605-2007-3	56.7 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2015	
2	NDC:68605-2007-4	106.3 g in 1 JAR; Type 0: Not a Combination Product	02/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/01/2015	

Labeler - ABBE Laboratories, Inc. (781745286)

Establishment

Name	Address	ID/FEI	Business Operations
ABBE Laboratories, Inc.		781745286	manufacture(68605-2007)

Revised: 1/2022

ABBE Laboratories, Inc.