

RASH BUSTER- zinc oxide paste paste
Jeshurun Pharmaceutical LLC

Use in the specific population

Warnings

- For adult use only
- For external use only
- Do not get into eyes
- Stop use if you are allergic to any of these ingredients
- Stop use and see doctor if condition worsen or symptoms last more than seven days or dry up and occur again within a few days
- Do not use on deep or punctured wounds, animal bites or serious burns

Inactive ingredients

Inactive Ingredients

Dicaprylyl Carbonate, Cod liver Oil, Coco-Caprylate, Cetearyl Olivatate, Sorbitan Olivatate, Polyhydroxystearic Acid , Menthol, Benzyl Alcohol, Oryza Sativa Bran Extract, Helianthus Annuus Extract, Ethylhexylglycerin, Tocophenol, Rosmarinus Officinalis Leaf Extract.

Dosage and administration

Directions

- Change wet diaper promptly, clean the diaper area and allow to dry.
- Apply the product liberally as often as necessary, with each diaper change especially at bedtime or anytime when exposure to wet diapers may be prolonged.

Precaution section

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center (1-800-222-1222) right away

Adverse reactions

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- Do not use on deep or punctured wounds, animal bites or serious burns

Indication & usage

Uses

- Helps relieve chafed, chapped or cracked skin
- Helps treat and prevent adult diaper rash and bed sores
- Helps protect from wetness

OTC- Active ingredient

Drug Facts

Active Ingredients Purpose

Lanolin 5.17% Skin Protectant

White Petrolatum 66.49% Skin Protectant

Zinc Oxide 20.2% Skin Protectant

Health claim

NDC 83347-1844-1



RASH BUSTER

FOR RELIEF OF BED SORES AND RASHES

FOR EXTERNAL USE ONLY

NEW WT. 7.41oz (210g)

MADE IN USA

Keep out of children

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center (1-800-222-1222) right away

Purpose

Drug Facts

Active Ingredients Purpose

Lanolin 5.17% Skin Protectant

White Petrolatum 66.49% Skin Protectant

Zinc Oxide 20.2% Skin Protectant

Ask doctor

Warnings

- For adult use only
- For external use only
- Do not get into eyes
- Stop use if you are allergic to any of these ingredients
- Stop use and see doctor if condition worsen or symptoms last more than seven days or dry up and occur again within a few days
- Do not use on deep or punctured wounds, animal bites or serious burns

Warnings

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- For adult use only
- For external use only
- Do not get into eyes
- Stop use if you are allergic to any of these ingredients
- Stop use and see doctor if condition worsen or symptoms last more than seven days or dry up and occur again within a few days
- Do not use on deep or punctured wounds, animal bites or serious burns

LABEL AND DRUG FACTS

NDC 83347-1844-1

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Drug Facts

Active Ingredients Purpose

Lanolin 5.17% — Skin Protectant
White Petrolatum 66.49% — Skin
Protectant
Zinc Oxide 20.2% — Skin Protectant

Uses

- Helps relieve chafed, chapped or cracked skin
- Helps treat and prevent adult diaper rash and bed sores
- Helps protect from wetness

Warnings

- For adult use only
- Do not get into eyes
- Stop use if you are allergic to any of the ingredients listed above
- Stop use and see doctor if condition worsens or symptoms last more than seven days or dry up and occur again within a few days
- Avoid contact with open wounds, burns, animal bites or serious injuries

Directions

- Charge wet diaper promptly, clean off feces and residue of old ointment.
- Apply liberally as often as necessary, with each diaper change especially at bedtime or anytime when exposure to wet diapers may be prolonged.

Storage

Protect from light and store at room temperature.

Inactive Ingredients

Dicaprylyl Carbonate, God Liver Oil, Coco-Caprylate, Cetearyl Olivate, Sorbitan Oliviate, Polyhydroxyrisearic Acid, Stearic Acid, Polysorbate 20, Saffra Bran Extract, Helianthus Annuus Extract, Ethylhexylglycerin, Tocophenol/Romarinus Officinalis Leaf Extract.

Keep out of reach of children

If swallowed get medical help or call Poison Control Center
(1-800-222-1222) right away.

LOT:

EXPIRE:

Distributed By:
JESHURUN PHARMACEUTICAL LLC
Ravenna, OH 44266

Inquiries:

jeshurunpharmaceuticals@gmail.com

RASH BUSTER

zinc oxide paste paste

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83347-1844
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	42.42 g in 210 g
WHITE PETROLATUM (UNII: B6E5W8RQJ4) (WHITE PETROLATUM - UNII:B6E5W8RQJ4)	WHITE PETROLATUM	139.629 g in 210 g
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	10.857 g in 210 g

Inactive Ingredients

Ingredient Name	Strength
COD LIVER OIL (UNII: BBL281NWFQ)	

Product Characteristics

Color	white (White Paste)	Score	
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Shape		Size	
Flavor		Imprint Code	
Contains			
Packaging			
#	Item Code	Package Description	Marketing Start Date
1	NDC:83347-1844-1	210 g in 1 JAR; Type 0: Not a Combination Product	05/01/2023
Marketing Information			
Marketing Category	Application Number or Monograph Citation		Marketing Start Date
OTC Monograph Drug	M016		05/01/2023

Labeler - Jeshurun Pharmaceutical LLC (092600853)

Registrant - Jeshurun Pharmaceutical LLC (092600853)

Establishment			
Name	Address	ID/FEI	Business Operations
Chae Organics, LLC		828138375	manufacture(83347-1844)

Revised: 11/2023

Jeshurun Pharmaceutical LLC