

VITABATH BABY ECZEMA CARE INTENSIVE BALM- colloidal oatmeal cream
Vitabath 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.

Vitabath Baby Eczema Care Intensive Balm

Active Ingredients

Colloidal Oatmeal 1% w/w

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

Directions: Apply as needed.

OTHER INFORMATION

Other Information: •Remove quality seal. •Do not use if quality seal is broken. •Protect from excessive heat (40°C/104°F).

Inactive Ingredients

Purified Water

Glycerin

Cetearyl Alcohol

Isopropyl Palmitate

Cetyl Alcohol

Caprylic/Capric Triglyceride

Sodium Stearoyl Glutamate

Stearic Acid

Benzyl Alcohol

Diheptyl Succinate

Potassium Phosphate Monobasic
 Capryloyl Glycerin/Sebacic Acid Copolymer
 Citric Acid
 Sodium Hydroxide
 Benzoic Acid
 Dehydroacetic Acid
 Tocopherol
 Avena Sativa (Oat) Kernel Extract
 Avena Sativa (Oat) Kernel Oil
 Ceramide NP
 Dipotassium Phosphate

Questions? Call toll-free 1-888-673-3377



VITABATH BABY ECZEMA CARE INTENSIVE BALM

colloidal oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73172-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	

TOCOPHEROL (UNII: R0ZB2556P8)
OAT KERNEL OIL (UNII: 3UVP41R77R)
BENZOIC ACID (UNII: 8SKN0B0MM)
OAT (UNII: Z6J799EAJK)
CERAMIDE NP (UNII: 4370DF050B)
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)
DIBASIC POTASSIUM PHOSPHATE (UNII: CI71S98N1Z)
DIHEPTYL SUCCINATE (UNII: 057N7SS26Y)
WATER (UNII: 059QF0KO0R)
GLYCERIN (UNII: PDC6A3C0OX)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)
CETYL ALCOHOL (UNII: 936JST6JCN)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)
STEARIC ACID (UNII: 4ELV7Z65AP)
BENZYL ALCOHOL (UNII: LKG8494WBH)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73172-003-01	312 g in 1 JAR; Type 0: Not a Combination Product	06/13/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/13/2019	

Labeler - Vitabath Inc. (203461637)

Establishment

Name	Address	ID/FEI	Business Operations
Canadian Custom Packaging Comapany		207062514	manufacture(73172-003)