

CERAVINE ORIGINAL MOISTURIZING MULTI-PURPOSE- oatmeal jelly
Biosstandard 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

Active ingredient

Colloidal Oatmeal (0.1%)

Purpose

Skin Protectant

Uses

- Temporarily relieves pain and itching commonly associated with skin dryness
- Helps prevent and temporarily protects chafed, chapped or cracked skin

Warnings

- For external use only

Do not use on

cuts, scrapes, or broken skins

Stop use and ask a doctor

if irritation or rash persists.

Keep out of reach of children.

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

Directions

Apply generously as needed.

Other information

Store below 86 F (30 C)

Inactive ingredients

Ricinus Communis (Castor) Seed Oil, Helianthus Annus (Sunflower) Seed Oil, Olea Europaea (Olive)

Fruit Oil, Cera Alba (Beeswax), Hydrogenated Vegetable Oil, Tocopherol, Lavandula Angustifolia (Lavender) Oil, Colloidal Oatmeal

Principal Display Panel

Ceravine ORIGINAL

ALL NATURAL INGREDIENTS

Net Wt. 1.7 Fl.oz (50 ml)

MOISTURIZING MULTI-PURPOSE OIL JELLY



CERAVINE ORIGINAL MOISTURIZING MULTI-PURPOSE			
oatmeal jelly			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 140 3-0 20
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name		Basis of Strength	Strength	
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)		OATMEAL	0.0485 g in 50 g	
Inactive Ingredients				
Ingredient Name			Strength	
YELLOW WAX (UNII: 2ZA36H0S2V)				
OLIVE OIL (UNII: 6UYK2W1W1E)				
TOCOPHEROL (UNII: R0ZB2556P8)				
SUNFLOWER OIL (UNII: 3W1JG795YI)				
LAVENDER OIL (UNII: ZBP1YXW0H8)				
CASTOR OIL (UNII: D5340Y2I9G)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61403-020-01	50 g in 1 CARTON; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part347	07/24/2015	

Labeler - Biostandard Inc. (688735402)

Registrant - Biostandard Inc. (688735402)

Establishment

Name	Address	ID/FEI	Business Operations
Biostandard Inc.		688735402	manufacture(61403-020)

Revised: 7/2015

Biostandard Inc.