

TENA- zinc oxide protective cream lotion
SCA Personal Care 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 Ingredient

Zinc Oxide 10%

Purpose

Skin Protectant

Uses

- helps treat and prevent skin rashes due to incontinence
- protects chafed skin due to incontinence and helps seal out wetness

Warnings

For external use only.

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

When using this product •avoid contact with 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 immediately

Directions

- cleanse skin with TENA® Cleansing Cream and/or TENA® Washcloths
- apply cream sparingly and reapply as needed

Other information Store between 32° F and 85° F

Inactive ingredients: Acacia Decurrens Flower Wax, Caprylic/Capric Triglyceride, Citric Acid, Dicaprylyl Carbonate,

Ethylhexylglycerin, Glycerin, Helianthus Annuus (Sunflower) Seed Wax, Jojoba Esters, Magnesium Sulfate, PEG-8 Beeswax, Polyglycerin-3,

Polyglyceryl-3 Ricinoleate, Potassium Sorbate, Sodium Benzoate, Sodium Citrate, Sodium Gluconate, Sorbitan Caprylate, Sorbitan

Isostearate, Tocopherol, Vegetable Oil, Water.

LAGEENTUBES
Design for the Best

WHITE SLEEVE
 SHINY VARNISH

6 FLEXO PRINTING COLORS

- PEACH P. 7411
- ORANGE P. 196
- BLUE P. 294
- SILVER P. 677
- CYAN
- GREEN P. 376

CUST. CODE: TP9688CA100ML-1
LAGEEN CODE: 577515104
BARCODE UPC A AT 80%: 768702644013
COMPOSITE 100% 71634 V1 25.04.2017

This is to confirm we checked this PDF and approve it. Our signature authorizes Lageen - Tuboplast to produce this item according to the texts, colors, images, codes and placements in this PDF. This version voids and replaces the previous one.
Signature: _____
Date: _____

The blue block is the eye mark 2 mm from edge

7 mm lacquer free area

8 mm

14 mm

9 mm

TUBE LENGTH 150 mm
SLEEVE LENGTH 155 mm (additional 5mm for neck)
Diam. .40

For checking only!

TENA
Protective Cream

10% zinc oxide
3.4 fl oz
100 ml

Irritated & sensitive skin
Scent free

Drug Facts
Active Ingredient: Zinc Oxide 10%
Purpose: Skin Protection

Directions
Apply neat and sparingly to clean skin. Reapply frequently. Wash skin after use. Do not use on open wounds or blisters. Do not use on irritated skin. Do not use on sunburned skin. Do not use on chapped skin. Do not use on dry skin. Do not use on cracked skin. Do not use on peeling skin. Do not use on scaly skin. Do not use on itchy skin. Do not use on sore skin. Do not use on tender skin. Do not use on sensitive skin. Do not use on inflamed skin. Do not use on infected skin. Do not use on damaged skin. Do not use on broken skin. Do not use on raw skin. Do not use on oozing skin. Do not use on weeping skin. Do not use on bleeding skin. Do not use on oiled skin. Do not use on greasy skin. Do not use on sticky skin. Do not use on sweaty skin. Do not use on oily skin. Do not use on shiny skin. Do not use on dry skin. Do not use on flaking skin. Do not use on peeling skin. Do not use on cracking skin. Do not use on itching skin. Do not use on burning skin. Do not use on stinging skin. Do not use on painful skin. Do not use on swollen skin. Do not use on red skin. Do not use on white skin. Do not use on dark skin. Do not use on light skin. Do not use on medium skin. Do not use on fair skin. Do not use on tan skin. Do not use on brown skin. Do not use on black skin. Do not use on any skin.

Manufactured for: SCA PERSONAL CARE, NEW London, NH
Distributed by: SCA PERSONAL CARE, 880 Laurel Drive, North Andover, MA 01855
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CONTACT: Peter Glaza TELEPHONE: 267-338-2068 E-MAIL: peter.glaza@sgsco.com	CLIENT: SCA PERSONAL CARE CLIENT CONTACT: Norma Jeanne Jordan	DESIGN & LAYOUT BY: SGS	Rev. No. 0
JOB NUMBER: 4580734	PROJECT: Shield	Material Master #: N/A	Issue Date: 03.29.2017
DATE: 03/29/2017	PRODUCT NAME: TENA Protective Cream US Scent Free 64401-03	UPC: 7 68702 64401 3	Revised by/Data: pg/4.4.17
		COLORS	Varnish
			<input type="checkbox"/>
		1 2 3 4 5 6 7 8 9	8 = 8 Stations

V
Only one blue P. 294
will be used in print.

TENA
zinc oxide protective cream lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59608-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)		ZINC CATION	10 g in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
GLYCERIN (UNII: PDC6A3C0OX)				
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)				
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)				
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)				
YELLOW WAX (UNII: 2ZA36H0S2V)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)				
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
SODIUM GLUCONATE (UNII: R6Q3791S76)				
SORBITAN (UNII: 6O92ICV9RU)				
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)				
TOCOPHEROL (UNII: R0ZB2556P8)				
CORN OIL (UNII: 8470G57WFM)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59608-003-10	100 mL in 1 TUBE; Type 0: Not a Combination Product	06/07/2017	
2	NDC:59608-003-05	5 mL in 1 TUBE; Type 0: Not a Combination Product	06/07/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	06/07/2017		

Labeler - SCA Personal Care Inc. (790100549)