

SKIN SAKE SURFACE PROTECTANT - dimethicone ointment

Skin Sake, LLC

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

Drug Facts

Active Ingredient

Dimethicone 2%

Purpose

Skin Protectant

Keep out of reach of children

Keep out of reach of children.

Uses

- Helps soothe, treat, and prevent ulcer-prone areas, cracked skin, rashes
- Repels wetness
- Protects delicate skin
- Relieves chapped, moist areas
- Prevents friction

Warnings

For external use only.

When using this product, do not get into eyes.

Stop and ask a doctor if condition worsens, symptoms last more than 7 days, or clear up and occur again within a few days.

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

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

Directions

Cleanse and dry area. Apply liberally as often as necessary, at least 4 or 5 times per day. Re-apply as needed.

Store between 15° -30° C, (59° -86° F)

Inactive ingredients

Aloe Barbadensis Extract, Acidium Boricum, Castor Oil, Cholecalciferol (Vitamin D), Cod Liver Oil, Green 6, Microcrystalline Wax, Mineral Oil, Myroxylon pereirae (Balsam Peru) Resin, Red 17, Vitamin A, Vitamin E, White Petrolatum, White Wax, Yellow 11

Product Label

www.skinsake.com

SKIN SAKE

Surface Protectant

PHARMACIST FORMULATED

Soothes and Prevents:

Ulcer-Prone Areas
Reddened/Cracked Skin
Incontinent Rashes
Chafed Areas

Repels Wetness
Vitamin A, D, E, and Aloe

NET WT 4OZ SP02

Manufactured for:

Skin Sake

P.O. Box 390

Hamburg, AR 71646

1-888-853-5544

681441-00

WWW.SKINSAKE.COM

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Surface Protectant

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Net Wt 4oz

SP02

SKIN SAKE SURFACE PROTECTANT

dimethicone ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43447-4410
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	2.272 g in 113.6 g
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Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BORIC ACID (UNII: R57ZHV85D4)	
CASTOR OIL (UNII: D5340Y2I9G)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
COD LIVER OIL (UNII: BBL281NWFG)	
D&C GREEN NO. 6 (UNII: 4QP5U84YF7)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
MINERAL OIL (UNII: T5L8T28FGP)	
BALSAM PERU (UNII: 8P5F881OCY)	
D&C RED NO. 17 (UNII: ND733RX3JN)	
VITAMIN A (UNII: 81G40H8B0T)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
PETROLATUM (UNII: 4T6H12BN9U)	
WHITE WAX (UNII: 7G1J5DA97F)	
D&C YELLOW NO. 11 (UNII: 44F3HYL954)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43447-4410-0	113.6 g in 1 TUBE		
2	NDC:43447-4410-2	100 in 1 BOX		
2	NDC:43447-4410-1	8 g in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/01/2009	

Labeler - Skin Sake, LLC (195912717)

Registrant - Skin Sake, LLC (195912717)

Establishment

Name	Address	ID/FEI	Business Operations
Memphis Contract Packaging, Inc.		185390010	manufacture(43447-4410)