

SKIN SAKE - petrolatum 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

White Petrolatum

Purpose

Soothes, Treats, Prevents,

Skin Irritations

Chafed Areas

Incontinent Rashes

Pressure Sores

Keep out of reach of children

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Uses

- Helps soothe, treat , and prevent skin breakdown
- Repels wetness
- Protects delicate skin
- Relieves chapped, moist or irritated 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 puncture wounds, animal bites, serious burns.

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

Directions

Cleanse and dry area. Apply a thin layer to skin as often as necessary.
Store between 15° - 30° C, (59° - 86° F)

Inactive ingredients

Peruvian Balsam, Aloe, Acidum Boricum, Vitamin E (Tocopherol), Zinc Oxide, Mineral Oil, Castor Oil, White Beeswax.

Product Label

NDC # 43447-2071-1

SKIN®Sake ointment

Soothes, Treats, Prevents

Skin Irritations

Chafed Areas

Incontinence Rashes

Pressure Sores

Skin Protectant

Moisture Barrier

Aloe and Vit. E Added

with Natural Peruvian Balsam

Net Wt 2.5 oz (71g)

Manufactured by:

SKIN SAKE, LLC

P.O. Box 390, Hamburg, AT 71646

1-888-853-5544 skinsake.com

NDC 43447-2071-1

SKIN SAKE

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442071-02

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SKIN SAKE

petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43447-2071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9 U) (PETROLATUM - UNII:4T6H12BN9 U)	PETROLATUM	23 g in 71 g

Inactive Ingredients

Ingredient Name	Strength
BALSAM PERU (UNII: 8P5F881OCY)	
ALOE (UNII: V5VD430YW9)	
BORIC ACID (UNII: R57ZHV85D4)	

.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)

ZINC OXIDE (UNII: SOI2LOH54Z)

MINERAL OIL (UNII: T5L8T28FGP)

CASTOR OIL (UNII: D5340Y2I9G)

WHITE WAX (UNII: 7G1J5DA97F)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43447-2071-1	71 g in 1 TUBE		
2	NDC:43447-2071-0	100 in 1 BOX		
2	NDC:43447-2071-2	2 g in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	12/01/2005	

Labeler - Skin Sake, LLC (195912717)

Registrant - Skin Sake, LLC (195912717)

Establishment

Name	Address	ID/FEI	Business Operations
Memphis Contract Packaging, Inc.		185390010	manufacture(43447-2071)

Revised: 4/2013

Skin Sake, LLC