SIMPLY RIGHT BODY CARE DAILY MOISTURIZING- dimethicone lotion SAM'S WEST 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

DIMETHICONE 1.3%

PURPOSE

SKIN PROTECTANT

USES

TEMPORARILY PROTECTS AND HELPS RELIEVE CHAPPED OR CRACKED SKIN AND HELPS PROTECT FROM THE DRYING EFFECTS OF WIND AND COLD.

WARNINGS

FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE THOROUGHLY WITH WATER.

STOP USING THIS PRODUCT AND ASK A DOCTOR IF

IRRITATION OR REDNESS DEVELOPS AN DLASTS MORE THAN SEVEN DAYS, OR IF IT CLEARS UP AND RECURS WITHIN A FEW DAYS.

KEEP OUT OF REACH OF CHILDREN.

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

APPLY AS NEEDED.

INACTIVE INGREDIENTS:

WATER (AQUA), GLYCERIN, DISTEARYLDIMONIUM CHLORIDE, PETROLATUM, ISOPROPYL PALMITATE, CETYL ALCOHOL, AVENA SATIVA (OAT) KERNEL FLOUR, BENZYL ALCOHOL, SODIUM CHLORIDE, DMDM HYDANTOIN, METHYLPARABEN, PROPYLPARABEN.

QUESTIONS OR COMMENTS?

1-888-301-0332



SIMPLY RIGHT BODY CARE DAILY MOISTURIZING

dimethicone lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-324
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	13 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
DISTEARYLDIMO NIUM CHLO RIDE (UNII: OM9 573ZX3X)			
PETROLATUM (UNII: 4T6H12BN9U)			
ISOPROPYL PALMITATE (UNII: 8 CRQ2TH63M)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
OATMEAL (UNII: 8 PI54V663Y)			
BENZYL ALCOHOL (UNII: LKG8494WBH)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
DMDM HYDANTO IN (UNII: BYR0546 TOW)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-324-02	74 mL in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	02/06/2013		

Labeler - SAM'S WEST INC. (051957769)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture (68196-324)	

Revised: 2/2013 SAM'S WEST INC.