

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 AND LASTS 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.

OTHER INFORMATION

STORE AT ROOM TEMPERATURE.

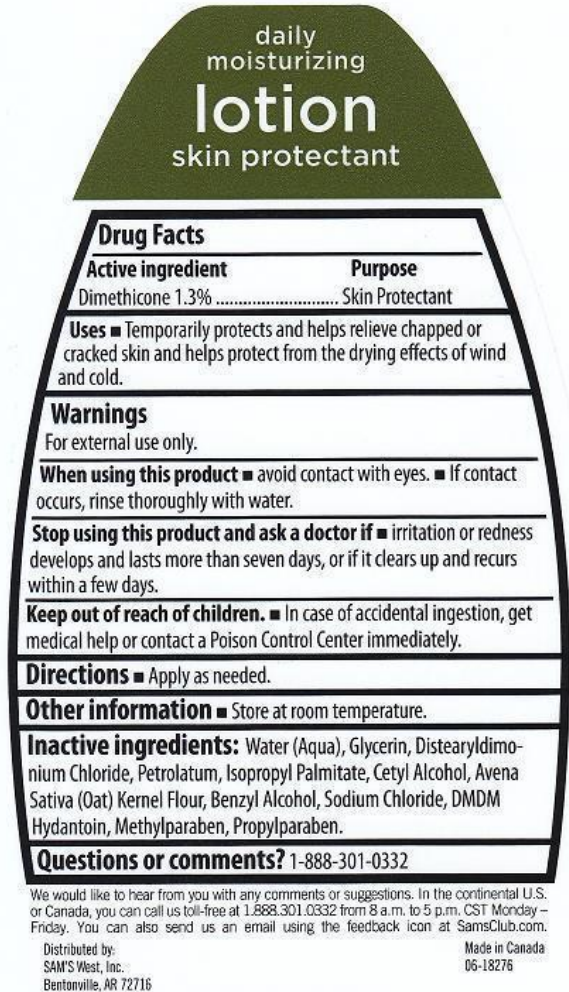
INACTIVE INGREDIENTS:

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

LABEL COPY



SIMPLY RIGHT BODY CARE DAILY MOISTURIZING

dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68 196-324
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	13 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
PETROLATUM (UNII: 4T6H12BN9U)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
OATMEAL (UNII: 8PI54V663Y)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-324-24	710 mL in 1 BOTTLE, PLASTIC		

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.