EQUALINE- dimethicone lotion SUPERVALU 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

CONDITION WORSENS, OR IF SYMPTOMS LAST MORE THAN 7 DAYS, OR IF THEY CLEAR UP AND OCCUR AGAIN 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:

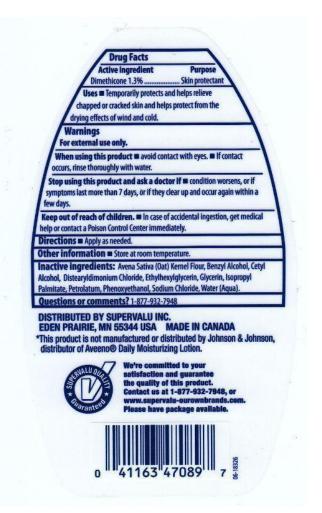
AVENA SATIVA (OAT) KERNEL FLOUR, BENZYL ALCOHOL, CETYL ALCOHOL, DISTEARYLDIMONIUM CHLORIDE, ETHYLHEXYLGLYCERIN, GLYCERIN, ISOPROPYL PALMITATE, PETROLATUM, PHENOXYETHANOL, SODIUM CHLORIDE, WATER (AQUA).

QUESTIONS OR COMMENTS?

1-877-932-7948

LABEL COPY





EQUALINE

dimethicone lotion

Drod	net	Infor	mation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41163-358

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients			
Ingredient Name	Strength		
OATMEAL (UNII: 8PI54V663Y)			
BENZYL ALCOHOL (UNII: LKG8494WBH)			

CETYL ALCOHOL (UNII: 936JST6JCN)		
DISTEARYLDIMO NIUM CHLO RIDE (UNII: OM9573ZX3X)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
ISOPROPYL PALMITATE (UNII: 8 CRQ2TH63M)		
PETROLATUM (UNII: 4T6H12BN9U)		
PHENO XYETHANO L (UNII: HIE492ZZ3T)		
SO DIUM CHLO RIDE (UNII: 451W47IQ8X)		
WATER (UNII: 059QF0KO0R)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:41163-358-12	354 mL in 1 BOTTLE, PLASTIC		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	0 1/15/20 13		

Labeler - SUPERVALU INC. (006961411)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(41163-358)	

Revised: 1/2013 SUPERVALU INC.