

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

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| 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 |
|--|-------------------|---------------|
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 13 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------------|----------|
| OATMEAL (UNII: 8PI54V663Y) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |

| | |
|---|--|
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| SODIUM CHLORIDE (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 | 01/15/2013 | |

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) |