

ULTIMATE SKIN PROTECTANT DERMA SHIELD- dimethicone aerosol
Fleet Laboratories LTD

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.

Ultimate Skin Protectant Derma Shield

Active ingredient Purpose

Dimethicone 2.7% Skin Protectant

Uses

- Helps prevent and temporarily protects and helps relieve chafed, chapped or cracked skin
- Helps prevent and protect from the drying effects of wind and cold weather

Keep out of reach of children

Stop use and ask a doctor if:

- condition worsens
- symptoms last more than 7 days or clear up again within a few days

Warnings

For external use only

Flammable:

- Do not use near flame or spark or while smoking
- Contents under pressure
- Do not puncture or incinerate
- Do not store at temperature above 120°F

Directions

- Apply as needed
- Children under 6 months: ask a doctor
- Wash and dry skin area
- Shake can vigorously
 - Invert can and apply "golf Ball" size amount in palm
 - Rub thoroughly onto the skin
 - Allow to dry

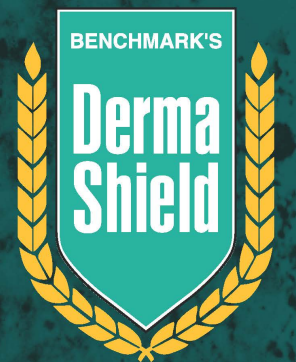
Inactive ingredients Water, Propane, Butane, Palmitic acid, Palm Kernel acid, Isopropyl Myristate, Glycerin, VP/VA Copolymer, Isobutane, Triethanolamine, Cetyl Alcohol, Cetearyl Alcohol, Ceteareth-20, Hydroxyethylcellulose, Perfluorinated Polyether, Aloe Barbadosis Leaf Juice, Tocopheryl Acetate, Lanolin, Tetrasodium EDTA, Propylene Glycol Diazolidinyl Urea, Methylparaben, Propylparaben, Sodium Benzoate, Potassium Sorbate, Citric Acid.

Benchmark's

DermaShield

The Ultimate Skin Protectant

Net Weight 17 oz(1lb 1 oz) (482g)



THE ULTIMATE SKIN PROTECTANT™

Net Weight
17oz (1lb 1oz) (482g) e

Manufactured in the United Kingdom

Expiration date and lot number
printed on container

Provides a non-toxic and
non-greasy, invisible layer
on all skin areas.

Helps maintain the skin's
natural moisture balance.

Gives up to four hours
maximum protection
(Duration of protection is
dependent upon proper
application).

Withstands repeated
washings.

Allows skin to breathe
and perspire naturally.

Is safe for all skin areas.

Clinically and laboratory
tested.

Can be used underneath
gloves.

CFC Free.



Drug Facts

Active ingredient	Purpose
Dimethicone 2.7%	Skin protectant

Uses

- helps prevent and temporarily protects and helps relieve chafed, chapped or cracked skin
- helps prevent and protect from the drying effects of wind and cold weather

Warnings

For external use only

Flammable: ■ Do not use near flame or spark or while smoking

- Contents under pressure
- Do not puncture or incinerate
- Do not store at temperature above 120°F

When using this product ■ do not get into eyes

Stop use 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 or puncture wounds ■ animal bites

- serious burns

Keep out of reach of children

Directions

- Apply as needed
- Children under 6 months: ask a doctor
- Wash and dry skin area
- Shake can vigorously
- Invert can and apply "golf ball" size amount in palm
- Rub thoroughly onto the skin
- Allow to dry

Inactive ingredients

Water, Propane, Butane, Palmitic acid, Palm Kernel acid, Isopropyl Myristate, Glycerin, VP/VA Copolymer, Isobutane, Triethanolamine, Cetyl Alcohol, Cetearyl Alcohol, Ceteareth-20, Hydroxyethylcellulose, Perfluorinated Polyether, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Lanolin, Tetrasodium EDTA, Propylene Glycol Diazolidinyl Urea, Methylparaben, Propylparaben, Sodium Benzoate, Potassium Sorbate, Citric Acid.

Distributed by:
Derma Shield, Inc.
1090 Bailey Hill Rd, Suite B
Eugene, OR 97402
385-313-0795

ULTIMATE SKIN PROTECTANT DERMA SHIELD

dimethicone aerosol

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70233-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	2.7 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ISOBUTANE (UNII: BXR49TP611)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

EDETATE SODIUM (UNII: MP1J8420LU)
LANOLIN (UNII: 7EV65EAW6H)
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)
PALM KERNEL ACID (UNII: 79P21R4317)
COPOVIDONE K25-31 (UNII: D9C330MD8B)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
GLYCERIN (UNII: PDC6A3C0OX)
HYDROXYETHYL CELLULOSE (4000 MPAS AT 1%) (UNII: ZYD53NBL45)
METHYLPARABEN (UNII: A2I8C7HI9T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SODIUM BENZOATE (UNII: OJ245FE5EU)
PALMITIC ACID (UNII: 2V16EO95HI)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
TROLAMINE (UNII: 9O3K93S3TK)
WATER (UNII: 059QF0KO0R)
CETYL ALCOHOL (UNII: 936JST6JCN)
PERFLUOROPOLYMETHYLISOPROPYL ETHER (UNII: X6324K3MBW)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
PROPANE (UNII: T75W9911L6)
BUTANE (UNII: 6LV4FOR43R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70233-010-01	482 g in 1 CAN; Type 0: Not a Combination Product	10/14/2019	
2	NDC:70233-010-02	170 g in 1 CAN; Type 0: Not a Combination Product	10/14/2019	
3	NDC:70233-010-03	57 g in 1 CAN; Type 0: Not a Combination Product	10/14/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/14/2019	

Labeler - Fleet Laboratories LTD (217269489)

Establishment

Name	Address	ID/FEI	Business Operations
FLEET LABORATORIES LTD		217269489	manufacture(70233-010)