ALLANTOIN- advanced derma spray aerosol, spray
Premier Brands of America 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.

Advanced Derma Spray

Active ingredient

Allantoin 0.5%

Purpose

Skin Protectant

Uses

Temporarily protects and helps relieve chapped or cracked skin

Warnings

For external use only.

Contents under pressure. Do not puncture or incinerate. Do not store above 120 °F. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.

Do not use

- on deep or puncture wounds
- on animal bites
- on serious burns

When using this product

- avoid spraying in 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

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- shake well before using
- apply as needed
- spray product onto affected area(s) and massage into skin in a circular motion
- for scars on face or near eyes spray product into palm of hand and apply with fingertips

Other information

store at room temperature

Inactive ingredients

Water, Dimethyl Ether, Isostearyl Isostearate, Isopropyl Isostearate, PPG-3 Benzyl Ether Myristate, Pentaerythrityl Tetracaprylate/Caprate, Methylsilanol Hydroxyproline Aspartate, Glycerin, Butylene Glycol, Allium Cepa (Onion) Bulb Extract, Sucrose Palmitate, Glyceryl Stearate, Glyceryl Stearate Citrate, Sucrose, Mannan, Xanthan Gum, Cetyl Hydroxyethylcellulose, Rutin, Palmitoyl Tripeptide-1, Palmitoyl Tetrapeptide-7, Phaseolus Lunatus (Green Bean) SEed Extract, Phenoxyethanol, Fragrance, Potassium Sorbate, Salicylic Acid

Questions?

Call 1-866-964-0939

Principal Display Panel

Premier

Advanced Derma Spray

Allantoin 0.5% - Skin Protectant

Improves overall appearance of SCARS*
Improves the appearance of texture & smoothness on STRETCH MARKS*
Dermatologist tested
Paraben Free

Shake well before use.

Net WT 3 OZ (85 g)

NDC XXXXX-XXX-XX

Compare to Mederma® Advanced Scar Gel active ingredient*

Advanced DERMA SPRAY

Allantoin 0.5% - Skin Protectant

- Improves the overall appearance of scars†
- Improves the appearance of texture and smoothness on stretch marks†
- Dermatologist tested
- Paraben-free

Shake well before use

NET WT 3.0 OZ (85 g)

*This product is not manufactured or distributed by Merz, Pharmaceuticals, LLC, owner of the registered trademark Mederma®.

†Based on an 8-week, daily use consumer panel study

Advanced Derma Spray should be applied once a day for 8 weeks on new scars. Apply as soon as the wound has closed.

Drug Facts

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50-126XX-01
Questions? Call 1-866-964-0939 MADE IN USA WITH U.S. AND IMPORTED PARTS

ALLANTOIN

advanced derma spray aerosol, spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:56104-034
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.425 g in 85 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
DIMETHYL ETHER (UNII: AM13FS69BX)	
ISOSTEARYL ISOSTEARATE (UNII: IV0Z586Z4Y)	
PPG-3 BENZYL ETHER MYRISTATE (UNII: 8075L58MKO)	
PENTAERYTHRITYL TETRACAPRYLATE/TETRACAPRATE (UNII: 832C4KF14X)	
GLYCERIN (UNII: PDC6A3C0OX)	

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ONION (UNII: 492225Q21H)	
SUCROSE PALMITATE (UNII: 3OSQ643ZK5)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
SUCROSE (UNII: C151H8M554)	
YEAST MANNAN (UNII: 91R887N59P)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)	
RUTIN (UNII: 5G06TVY3R7)	
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
LIMA BEAN (UNII: 112YH1ZMX2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56104-034-85	85 g in 1 CAN; Type 0: Not a Combination Product	03/27/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/27/2018	

Labeler - Premier Brands of America Inc. (080051232)

Revised: 3/2018 Premier Brands of America Inc.