

DEFLAME- allantoin cream
Noon Aesthetics M.R. 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.

DeFlame

Drug Facts

Active Ingredient

Allantoin 0.5%

Purpose

Skin Protectant

Uses

- Temporarily protects minor: skin irritation, cuts, scrapes, burns and helps protect and relieve chafed, chapped or cracked skin.

Warnings

For external use only.

Do not use on

- deep or puncture wounds, animal bites, serious burns.

When using this product

- avoid contact with eyes. In case of eye contact, flush with water.

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.

Directions

- Apply as needed.

Inactive Ingredients

Aqua, Propylene Glycol, Glycerin, Dimethyl Sulfone, Strontium Chloride Hexahydrate, Polydimethylsiloxane, Cetyl Alcohol, Glyceryl Stearate, Propanediol, Dipotassium

Glycyrrhizate, Polysorbate 20, PEG-40 Stearate, Laureth-4, Porphyridium Polysaccharide, Arnica Montana Flower Extract, sh-Oligopeptide-1 (EGF), sh-Oligopeptide-2 (IGF-1), sh-Polypeptide-1 (bFGF), sh-Polypeptide-9 (VEGF), sh-Polypeptide-11 (FGF-1), Bacillus/Folic Acid Ferment Filtrate Extract, Octyldodecyl Xyloside, Butylene Glycol, Sodium Hyaluronate, 1,2-Hexanediol, Acetyl Glutamine, Octyldodecanol, PEG-30 Dipolyhydroxystearate, Sorbitan Tristearate, Lecithin, Phenoxyethanol, Benzyl Alcohol, Caprylyl Glycol, Potassium Sorbate, Disodium EDTA, Sodium Benzoate.

Questions or comments?

Visit noonaesthetics.com or call Toll Free 1.833.666.6246

Dist by NOON Aesthetics

TLV, 62153

PRINCIPAL DISPLAY PANEL - 50 ml Tube Carton

noon

AESTHETICS

DeFlame

SKIN PROTECTANT

+ DERMSHIELD™

50 ml / 1.75 Fl. Oz. e

noonaesthetics.com



CORRECT | Br. Ac. Re. De®

PARACEUTICAL

Medicated Skin Gel Cream
Soothes irritated skin
Post-Procedure Treatment
Steroid-Free

Allantoin 0.5%



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Developed + Dist by NOON Aesthetics
TLV, 62153 | Made in Israel
noonaesthetics.com



CIRCLE HOLE SIZE
TO BE DETERMINED

DEFLAME

allantoin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78863-1270
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
STRONTIUM CHLORIDE HEXAHYDRATE (UNII: O09USB7Z44)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPANEDIOL (UNII: 5965N8W85T)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
LAURETH-4 (UNII: 6HQ855798J)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
OCTYLDODECYL XYLOSIDE (UNII: 8Z6VNR46QM)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
ACEGLUTAMIDE (UNII: 01J18G9G97)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO)	
SORBITAN TRISTEARATE (UNII: 6LUM696811)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78863-1270-1	1 in 1 CARTON	10/01/2023	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	10/01/2023	

Labeler - Noon Aesthetics M.R. Ltd (600185560)**Establishment**

Name	Address	ID/FEI	Business Operations
Noon Aesthetics M.R. Ltd		600185560	MANUFACTURE(78863-1270)

Revised: 9/2023

Noon Aesthetics M.R. Ltd