

DERMAGREEN SKIN CARE- allantoin, lidocaine cream
Healthy Gourmet Plus, Inc

DermaGreen Skin Care

Drug Facts

Active ingredients

Allantoin 1%

Lidocaine 1%

Purpose

Skin Protectant

External Analgesic

Uses

- for the temporary relief of pain associated with minor burns or minor skin irritations
- temporarily protects minor
- cuts
- scrapes
- burns
- temporarily protects chapped or cracked skin

Warnings

For external use only.

Do not use

- on deep or puncture wounds
- on animal bites
- on serious burns
- in large quantities, particularly over raw surfaces or blistered areas

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

Keep out of reach of children.

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


Directions

- Adults and children over 12 years: apply a thin layer to affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period.
- Children under 12 years: ask a doctor.

Inactive ingredients

African oil palm oil, almond oil, alpha-tocopheryl acetate, beeswax, bitter orange extract, buckthorn oil, C10-18 triglyceride, carrot root extract, evening primrose oil, frankincense extract, geranium extract, hydrogenated coconut oil, lavender extract, lemongrass extract, paraffin wax, patchouli oil, shea butter, stearic acid, sunflower oil, wheat germ oil, white flower oil, ylang-ylang extract.

Package Labeling:

Drug Facts Active ingredients Purpose Allantoin 1%.....Skin Protectant Lidocaine 1%.....External Analgesic	Drug Facts (continued) 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.	DISTRIBUTED BY: HEALTHY GOURMET PLUS INC. 1122 EAST 14TH BROOKLYN, NY 11230 UNITED STATES MADE IN ISRAEL	
Uses ■ for the temporary relief of pain associated with minor burns or minor skin irritations ■ temporarily protects minor ■ cuts ■ scrapes ■ burns ■ temporarily protects chapped or cracked skin	Directions ■ Adults and children over 12 years: apply a thin layer to affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period. ■ Children under 12 years: ask a doctor.	TO REPORT A SERIOUS ADVERSE EVENT, CONTACT THE DISTRIBUTOR AT THE ADDRESS ABOVE. CLOSE CAP TIGHTLY AFTER USE. STORE IN A COOL PLACE WHERE TEMPERATURES DO NOT EXCEED 95°F.	
Warnings For external use only. Do not use ■ on deep or puncture wounds ■ on animal bites ■ on serious burns ■ in large quantities, particularly over raw surfaces or blistered areas When using this product do not get into eyes.	Inactive ingredients African oil palm oil, almond oil, alpha-tocopheryl acetate, beeswax, bitter orange extract, buckthorn oil, C10-18 triglyceride, carrot root extract, evening primrose oil, frankincense extract, geranium extract, hydrogenated coconut oil, lavender extract, lemongrass extract, paraffin wax, patchouli oil, shea butter, stearic acid, sunflower oil, wheat germ oil, white flower oil, ylang-ylang extract.	Barcode Placeholder	

%1 Lidocaine + %1 Allantoin
 External Analgesic and Skin Protectant
 Provides temporary pain relief from burns

1 fl oz (30 mL)

DERMAGREEN SKIN CARE

allantoin, lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83363-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	10 mg in 1 mL
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALMOND OIL (UNII: 66YXD4DKO9)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CITRUS AURANTIUM FRUIT RIND (UNII: 055456JHI7)	

C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)
CARROT (UNII: L56Z1JK48B)
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)
FRANKINCENSE (UNII: R9XLF1R1WM)
GERANIUM ROBERTIANUM LEAF (UNII: 6H429I0Y3L)
HYDROGENATED COCONUT OIL (UNII: JY81OXM1OM)
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)
PARAFFIN (UNII: I9O0E3H2ZE)
POGOSTEMON CABLIN LEAF OIL (UNII: F3IN55X5PO)
SHEA BUTTER (UNII: K49155WL9Y)
STEARIC ACID (UNII: 4ELV7Z65AP)
SUNFLOWER OIL (UNII: 3W1JG795YI)
WHEAT GERM OIL (UNII: 14C97E680P)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83363-003-00	30 mL in 1 JAR; Type 0: Not a Combination Product	11/21/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	11/21/2023	

Labeler - Healthy Gourmet Plus, Inc (083200862)

Revised: 12/2023

Healthy Gourmet Plus, Inc