

**HAPRODERM WOUND GEL DRESSING WITH HYALURONIC ACID- dressing,
wound, occlusive
NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY**

Haproderm

DESCRIPTION: Haproderm is a soothing wound gel that is formulated for the dressing and management of superficial wounds, minor abrasions, pressure ulcers stage II - IV, 1st and 2nd degree burns, including sunburns, and radiation dermatitis. When applied properly to a wound hyaluronic acid adheres to tissue to prevent damage while supplying moisture to the cells. Medium molecular weight polysaccharides in aloe Vera moisturize and reduce inflammation. Proven therapeutic moisturizers, lipids, glycerin and allantoin, relieves dryness

INDICATIONS FOR USE

Under the supervision of a healthcare professional, Haproderm Gel is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. Haproderm Gel also helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

DESCRIPTION

Haproderm Gel is a non-sterile, off-white, low odor, fragrance free, topical product. The Haproderm Gel forms a physical barrier that helps to maintain a moist wound and skin environment. Haproderm Gel is a prescription medical device.

CONTRAINDICATIONS

Haproderm Gel is contraindicated in persons with a known hypersensitivity to any of the components of the formulation.

WARNINGS

Use only as directed. Keep out of the reach of children. Avoid contact with eyes. For topical use only. Not for ophthalmic use. Do not apply within four hours prior to a radiation session.

PRECAUTIONS AND OBSERVATIONS

- Haproderm Gel does not contain a sunscreen and should not be used prior to extended exposure to the sun.
- If clinical signs of infection are present, appropriate treatment should be initiated; use of Haproderm Gel may be continued during the anti-infective therapy.

INSTRUCTIONS FOR USE

Dispense Haproderm Gel into palm of hand and apply to affected area 3 times per day, or as directed by a physician. Massage gently into the skin until completely absorbed. If the skin is broken, cover with appropriate dressing Haproderm Gel is non-sterile.

INGREDIENTS

Allantoin
Aloe Barbadensis Leaf Extract
Caprylic/Capric Triglyceride
Carbomer
Ceteareth 20
Cetearyl Alcohol
Diazolidinyl Urea & Iodopropynyl Butylcarbamate
Dimethicone
Glycerin
Glycol Stearate
Hyaluronic Acid
Isopropyl Palmitate
Olea Europaea (Olive) Oil
Propylene Glycol
Tetrasodium EDTA
Triethanolamine
Water

HOW SUPPLIED

Haproderm Gel is available in 30g commercial pump dispenser.

CAUTION: Federal law restricts this device to sale by or on the order of a physician or other licensed health care practitioner.

Store between 59°F - 86°F (15°C - 30°C).

MANUFACTURED FOR:

NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY
Branchburg, NJ 08876

Label

HAPRODERM GEL

NET WEIGHT: 30G

NDC: 72678-020-07

Ingredients: Purified water, Aloe barbadensis leaf extract, Glycerin, Olea europaea (olive) oil, Caprylic/Capric triglyceride, Dimethicone, Cetearyl alcohol & cetareth-20, Hyaluronic acid, Glycol stearate, Propylene glycol, Allantoin, Isopropyl palmitate, Triethanolamine, Carbomer, Diazolidinyl urea & iodopropynyl butylcarbamate, Tetrasodium EDTA

Rx Only CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.



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Rx Only 72678-020-07



Haproderm

FOR TOPICAL USE ONLY
NOT FOR OPHTHALMIC USE

Net Wt.30g

Directions: Apply a small amount of Haproderm Gel in sufficient quantity to cover the affected skin area and allow to dry. Reapply up to 3 times per day (or as needed).

Storage: Store at 25° C (77° F); excursions permitted to 15° - 30° C (59° - 86° F). Protect from freezing [see USP Controlled Room Temperature].

WARNING: External use only. Do not use this product if you are allergic to any of the ingredients. Avoid contact with eyes. KEEP OUT OF REACH OF CHILDREN.



Lot No: C-7356

EXP: 1-2023

Manufactured For:
NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY
Branchburg, NJ 08876

HAPRODERM WOUND GEL DRESSING WITH HYALURONIC ACID

dressing, wound, occlusive

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	NHRIC:72678-020
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
HYALURONIC ACID (UNII: S270N0TRQY)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALLANTOIN (UNII: 344S277G0Z)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
EDETATE SODIUM (UNII: MP1J8420LU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:72678-020-07	30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
exempt device	MDA	07/30/2021	

Labeler - NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY (967054623)

Revised: 7/2021

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