

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

Halucort

DESCRIPTION: Halucort 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, Halucort 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. Halucort Gel also helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process

DESCRIPTION

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

CONTRAINDICATIONS

Halucort 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

- Halucort 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 Halucort Gel may be continued during the anti-infective therapy.

INSTRUCTIONS FOR USE

Dispense Halucort 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 Halucort Gel is non-sterile.

INGREDIENTS

Allantoin

Aloe Barbadensis Leaf Extract
Caprylic/Capric Triglyceride
Carbomer
Cetareth 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

Halucort 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

Rx only

Packaging

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.

Rx Only

72678-033-01

Halucort

FOR TOPICAL USE ONLY
NOT FOR OPHTHALMIC USE

Directions: Apply a small amount of Halucort 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



00372678033018

Net Wt.30g

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

nbgs
PHARMA

HALUCORT GEL DRESSING WITH HYALURONIC ACID

dressing, wound, occlusive

Product Information

| | | | |
|---------------------|-----------------------------|---------------------------|-----------------|
| Product Type | PRESCRIPTION MEDICAL DEVICE | Item Code (Source) | NHRIC:72678-033 |
|---------------------|-----------------------------|---------------------------|-----------------|

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 HOMO POLYMER, 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:72678-033-01 | 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 | NAD | 01/13/2020 | |

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