

**NELLY DEVUYST BIO MEDICAL BIOACNE ANTI-REDNESS SERUM 30 ML-
colloidal oatmeal cream
LABORATOIRES DRUIDE 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.

NELLY DEVUYST BIO MEDICAL BIOACNE ANTI-REDNESS SERUM 30 mL

DRUG FACTS

Active Ingredients

Colloidal Oatmeal 1.3%

Purpose

Skin Protectant

Uses

■ Temporarily protects and helps relieve minor skin irritations and itching due to eczema rash and dermatitis.

Warnings

For external use only

Do not use

Consult a healthcare practitioner if symptoms worsen or last for more than 7 days.

When using this product

keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

rash occurs.

Keep out of reach of children

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

Directions

- Apply to affected area as needed.

Other Information

Protect the product in this container from excessive heat and direct sun. Store the product at room temperature 20 to 25°C (68 to 77°F).

Inactive Ingredients

Aloe Barbadosis Leaf Juice*, C10-18 Triglycerides, Oenothera Biennis (Evening Primrose) Oil*, Coco-Caprylate, Curcuma Longa Extract*, Propanediol, Polyglyceryl-6 Distearate, Crataegus Oxyacantha Extract*, Crataegus oxyacantha (hawthorn), Glyceryl Stearate (2%), Nelumbo Nucifera Root Water, Jojoba Esters, Aspalathus Linearis Leaf Extract*, Sodium Stearoyl Glutamate, Polyglyceryl-3 Beeswax, Glycerin, Cetyl Alcohol, Tocopherol (Vitamin E), Salicylic Acid, Xanthan Gum, Benzyl Alcohol, Potassium Sorbate, Illicium Verum (Anise) Fruit/Seed Oil* , Sorbic Acid, Melaleuca Alternifolia (Tea Tree) Leaf Oil*, Sodium Hyaluronate, Zingiber Officinale (Ginger) Root Oil*, Glycogen.

*Certified organic.

Questions or Comments?

1-800-263-8888

Outside Canada or the United States dial **514-333-8282** or visit www.nellydevuyt.com

NELLY DEVUYST BIO MEDICAL BIOACNE ANTI-REDNESS SERUM 30 mL (NDC 71447-030-00)

THE BEST OF SCIENCE AND NATURE



BIO | MEDICAL



BIO | MEDICAL

BIOACNE ANTI-REDNESS SERUM SÉRUM ANTI-ROUGEURS



AIRLESS

1 fl. oz. - 30 ml e

NPN 80109704



Manufactured by / Fabriqué par
Laboratoires Nelly DeVuyt
Division of Laboratoires Desude Inc., Pointe-Clair,
QC H9R 1A8 Canada

Distributed by / Distribué par
7774672 CANADA INC. | DBA DermelCo
56 Laurent, Qc, H4S 1A7 Canada
t: +1 514.333.8282 | 1.800.263.8888
info@derme.ca | nellydevuyt.com

Dist. Europe:
Bio Evidence
46, Lot du Buisson, 33650 Saucats France
t: +33 1 85 14 92 90 | nellydevuyt.fr

Made in Canada | Fait au Canada

19461

BIOACNE ANTI-REDNESS SERUM

DRUG FACTS

ACTIVE INGREDIENTS **PURPOSE**
Colloidal Oatmeal 1.3% Skin protectant

USES:

Temporarily protects and helps relieve minor skin irritations and itching due to eczema rash and dermatitis

WARNINGS:

- For external use only
- Avoid contact with eyes.
- Consult a healthcare practitioner if symptoms worsen or last for more than 7 days.

DIRECTIONS:

- Apply to affected area as needed

OTHER INFORMATION:

Store the product at room temperature 20 to 25 °C (68 to 77 °F)

INACTIVE INGREDIENTS: Aloe Barbadosis Leaf Juice*, C10-18 Triglycerides, Oenothera Biennis (Evening Primrose) Oil*, Coco-Caprylate, Curcuma Longa Extract*, Propanediol, Polyglyceryl-6 Distearate, Crataegus Oxyacantha Extract*, Glyceryl Stearate (2%), Nelumbo Nucifera Root Water, Jujuba Esters, Agave Linnæus Leaf Extract*, Sodium Stearoyl Glutamate, Polyglyceryl-3 Beeswax, Glycerin, Cetyl Alcohol, Tocopherol (Vitamin E), Salicylic Acid, Xanthan Gum, Benzyl Alcohol, Potassium Sorbate, Ilicium Verum (Anise) Fruit/Seed Oil*, Sorbic Acid, Melaleuca Alternifolia (Tea Tree) Leaf Oil*, Sodium Hyaluronate, Zingiber Officinale (Ginger) Root Oil*, Glycogen.
*Certified organic

QUESTIONS OR COMMENTS? Call 1.800.263.8888
Outside Canada or US dial +1 514.333.8282
or visit www.nellydevuyt.com

BIOACNE SÉRUM ANTI-ROUGEURS

INGRÉDIENTS MÉDICINAUX : Faire d'avoine colloïdale* 1,3 %

RECOMMANDATIONS : Protéger et aide à soulager temporairement les démangeaisons et les irritations mineures cutanées provoquées par les rashes, l'eczéma, le surnage vésiculeux, herbe à puer, le surnage de l'Ouest et le surnage lacté, ainsi que par les morsures d'insectes

MODE D'EMPLOI : Appliquer sur la région atteinte au besoin

PRÉCAUTIONS ET MISES EN GARDE :

- Pour un usage externe seulement.
- Éviter tout contact avec les yeux.
- Consulter un praticien de soins de santé si les symptômes s'aggravent ou durent plus de 7 jours.

AUTRE RENSEIGNEMENTS:

Entopper le produit à la température ambiante 20-25°C (68-77°F)

QUESTIONS OU COMMENTAIRES!

Appeler 1.800.263.8888. En dehors du Canada ou U.S.A., composer le +1 514.333.8282 ou visiter nellydevuyt.com.

INGRÉDIENTS NON-MÉDICINAUX (INCI) : Aloe Barbadosis Leaf Juice*, C10-18 Triglycerides, Oenothera Biennis (Evening Primrose) Oil*, Coco-Caprylate, Curcuma Longa Extract*, Propanediol, Polyglyceryl-6 Distearate, Crataegus Oxyacantha Extract*, Glyceryl Stearate (2%), Nelumbo Nucifera Root Water, Jujuba Esters, Agave Linnæus Leaf Extract*, Sodium Stearoyl Glutamate, Polyglyceryl-3 Beeswax, Glycerin, Cetyl Alcohol, Tocopherol (Vitamin E), Salicylic Acid, Xanthan Gum, Benzyl Alcohol, Potassium Sorbate, Ilicium Verum (Anise) Fruit/Seed Oil*, Sorbic Acid, Melaleuca Alternifolia (Tea Tree) Leaf Oil*, Sodium Hyaluronate, Zingiber Officinale (Ginger) Root Oil*, Glycogen.

* Ingrédients from organic farming. / * Ingrédients issus de l'agriculture biologique.
77% of the total ingredients are from organic farming. / du total des ingrédients sont issus de l'agriculture biologique.

98% natural origin of total. / du total est d'origine naturelle.
COSMOS ORGANIC, certified by Ecocert Greenlife according to COSMOS standard available at <http://COSMOS.ecocert.com>
COSMOS ORGANIC, certifié par Ecocert Greenlife selon le référentiel COSMOS disponible sur <http://COSMOS.ecocert.com>



NELLY DEVUYST BIO MEDICAL BIOACNE ANTI-REDNESS SERUM 30 ML

colloidal oatmeal cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71447-030 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y) | OATMEAL | 1.3 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| COCO-CAPRYLATE (UNII: 4828G836N6) | |
| TURMERIC (UNII: 856YO1Z64F) | |
| PROPANEDIOL (UNII: 5965N8W85T) | |
| POLYGLYCERYL-6 DISTEARATE (UNII: Z35I17EQOP) | |
| HAWTHORN LEAF WITH FLOWER (UNII: 6OM09RPY36) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| NELUMBO NUCIFERA ROOT OIL (UNII: 382005USDH) | |
| JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL) | |
| ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU) | |
| SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024) | |
| YELLOW WAX (UNII: 2ZA36H0S2V) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| SALICYLIC ACID (UNII: O414PZ4LPZ) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| STAR ANISE FRUIT (UNII: CK15HA8438) | |
| SORBIC ACID (UNII: X045WJ989B) | |
| TEA TREE OIL (UNII: VIF565UC2G) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| GINGER OIL (UNII: SAS9Z1SVUK) | |
| GLYCOGEN (UNII: 309GSC92U1) | |
| ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|----------------------------|-----------------------------|---------------------------|
| 1 | NDC:71447-030-01 | 1 in 1 BOX | 10/14/2021 | |

| | | | | |
|------------------------------|---|---|-----------------------------|---------------------------|
| 1 | NDC:71447-030-00 | 30 g 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 | part347 | | 10/14/2021 | |

Labeler - LABORATOIRES DRUIDE INC (245815014)

Registrant - LABORATOIRES DRUIDE INC (245815014)

| | | | |
|-------------------------|----------------|---------------|----------------------------|
| Establishment | | | |
| Name | Address | ID/FEI | Business Operations |
| LABORATOIRES DRUIDE INC | | 245815014 | manufacture(71447-030) |

Revised: 10/2021

LABORATOIRES DRUIDE INC