

**NELLY DEVUYST BIO MEDICAL BIOACNE ANTI-REDNESS 50G- colloidal
oatmeal gel
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 GEL 50 G

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 Barbadensis Leaf Juice*, Arnica Montana Flower Extract*, Hypericum Perforatum Extract*, Propanediol, Octyldodecyl Myristate, Capparis Spinosa Fruit Extract, Xanthan Gum, Nelumbo Nucifera Root Water, Alpha-Glucan Oligosaccharide, Salicylic Acid, Glycerin (vegetal), Benzyl Alcohol, Aqua (Water), Sorbic Acid, Potassium Sorbate, Aesculus Hippocastanum (Horse Chestnut) Extract*, Parfum (Natural), Tocopherol (Vitamin E), Fructose, Inulin, Bisabolol.

*Certified organic.

Questions or Comments?

1-800-263-8888

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

NELLY DEVUYST BIO MEDICAL BIOACNE ANTI-REDNESS GEL 50G (NDC 71447-053-00)



BIO | MEDICAL



BIO | MEDICAL

BIOACNE

ANTI-REDNESS GEL
GEL ANTI-ROUGEURS



AIRLESS

1.76 oz. - 50 g e

NPN 80109134



19751

BIOACNE - ANTI-REDNESS GEL

DRUG FACTS

ACTIVE INGREDIENTS	PURPOSE
Colloidal Oatmeal 1.3%	Skin protectant

USES:

- Protects and temporarily helps relieve redness (itching and minor skin irritation caused by eczema, poison ivy, poison oak or poison sumac, and insect bites)

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 20-25 ° C (68-77 ° F)

INACTIVE INGREDIENTS: Aloe Barbadensis Leaf Juice*, Amica Montana Flower Extract*, Hypericum Perforatum Extract*, Propanediol, Octyldodecyl Myristate, Capparis Spinosa Fruit Extract, Xanthan Gum, Nelumbo Nucifera Root Water, Alpha-Glucan Oligosaccharide, Salicylic Acid, Glycerin (vegetal), Benzyl Alcohol, Aqua (Water), Sorbic Acid, Potassium Sorbate, Aesculus Hippocastanum (Horse Chestnut) Extract*, Parfum (Natural), Tocopherol (Vitamin E), Fructose, Inulin, Bisabolol.
*Certified organic

QUESTIONS OR COMMENTS?

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*Ingredients from Organic Farming. 79% of the total ingredients are from organic farming. 98% natural origin of total. COSMOS ORGANIC certified by Ecocert Greenlife according to COSMOS standard available at <http://COSMOS.ecocert.com>

*Ingrédients issus de l'agriculture biologique. 79% du total des ingrédients sont issus de l'agriculture biologique. 98% du total est d'origine naturelle. COSMOS ORGANIC certifié par Ecocert Greenlife selon le référentiel COSMOS disponible sur <http://COSMOS.ecocert.com>

BIOACNE - GEL ANTI-ROUGEURS

INGRÉDIENT MÉDICINAUX: Farine d'avoine colloïdale 1.3%

OBJECTIF: Protéger la peau

RECOMMANDATIONS: Protège et aide à soulager temporairement les rougeurs (les démangeaisons et les irritations mineures cutanées provoquées par l'eczéma, le sumac vénéneux (herbe à puce), le sumac lustré, 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.

AUTRES

RENSEIGNEMENTS: Entreposer le produit à la température ambiante de 20 - 25°C (68 - 77°F).

QUESTIONS OU COMMENTAIRES? Appeler 1.800.263.8888 Extérieur du Canada ou U.S.A. composer le +1 514.333.8282 ou visiter nellydevuyst.com.

Manufactured by / Fabriqué par
Laboratoires Nelly De Vuyst®
Montreal (Qc), Canada

Distributed by / Distribué par
Derme&Co
St. Laurent (Qc), H4S 1A7 Canada
+1 514.333.8282
1 800.263.8888
info@derme.ca
nellydevuyst.com

Dist. Europe
46 Lot du Branet
33650 Saucats France
T: +33 1 85 14 92 90
nellydevuyst.fr



Made in Canada /
Fabriqué au Canada

colloidal oatmeal gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71447-053
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
LEVOMENOL (UNII: 24WE03BX2T)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CAPER BERRY (UNII: 7G4C45EE8C)	
PROPANEDIOL (UNII: 5965N8W85T)	
NELUMBO NUCIFERA ROOT OIL (UNII: 382005USDH)	
GLYCERIN (UNII: PDC6A3C0OX)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SORBIC ACID (UNII: X045WJ989B)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
.ALPHA.-GLUCAN OLIGOSACCHARIDE (UNII: S95658MI3W)	
WATER (UNII: 059QF0K00R)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
FRUCTOSE (UNII: 6YSS42VSEV)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)	
OCTYLDODECYL MYRISTATE (UNII: S013N99GR8)	
INULIN (UNII: JOS53KRJ01)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71447-053-00	50 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/01/2022	

Labeler - LABORATOIRES DRUIDE INC (245815014)

Registrant - LABORATOIRES DRUIDE INC (245815014)

Establishment

Name	Address	ID/FEI	Business Operations
LABORATOIRES DRUIDE INC		245815014	manufacture(71447-053)

Revised: 1/2022

LABORATOIRES DRUIDE INC