

NELLY DEVUYST MICELLAR FOAM BIOACNE- salicylic acid liquid
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 MICELLAR FOAM BIOACNE 150mL

DRUG FACTS

Active Ingredients

Salicylic acid 0.5%

Purpose

Acne Treatment

Uses

Helps prevent new acne pimples from forming.

Warnings

For external use only.

When using this product

▪ avoid contact with eyes. If contact occurs, rinse thoroughly with water ▪ Skin irritation and dryness are more likely to occur when using another topical acne product at the same time. If irritation occurs, use only one product at a time.

Stop use

and ask a doctor if

▪ you develop severe irritation, burning or itching of the skin ▪ for more severe cases and or if improvement is not apparent within 6 to 8 weeks ▪ If you develop hives, swelling of eyes and mouth, blistering or difficulty breathing, get medical help right away.

Keep out of reach of children.

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

Directions

- For new users: apply product to a small area once to test if you are sensitive to this product.
- If no discomfort occurs, moisten skin with warm water.
- Dispense two full pumps of product into palm of hand, apply by gently massaging over the entire affected area, rinse thoroughly and pat dry.

- Avoid contact with eyes. If contact occurs, rinse eyes with water.
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.
- If bothersome dryness, irritation or peeling occurs, reduce application to every other day.

Other information

Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

Aloe Barbadensis Leaf Juice*, Arctium Lappa Root Extract*, Urtica Dioica (Nettle) Extract*, Lavandula Angustifolia (Lavender) Flower Extract*, Propanediol, Coco-Glucoside, Glycerin, Silver Citrate, Arginine, Magnolia Officinalis Bark Extract, Michelia Alba Flower Oil, Citrus Aurantifolia (Lime) Oil*, Lavandula Hybrida Oil*, Tea Tree Leaf Oil*, Citrus Aurantium Dulcis (Orange) Peel Oil Expressed*, Sodium Gluconate, Levulinic Acid, Sodium Levulinate, Potassium Sorbate, Citric Acid, Aqua.

Certified organic*

Questions or Comments?

Call +1 800-263-8888

Outside Canada or United States, dial +1 514-333-8282, or visit www.nellydevuyst.com

Distributed By

7774672 Canada Inc (Derme & Co)

4980 Chemin Bois Franc

St. Laurent, QC H4S 1A7

Canada

+1 514-333-8282, +1 800-263-8888

www.nellydevuyst.com

Made in Canada

NELLY DEVUYST MICELLAR FOAM BIOACNE 5.07 FL.OZ (150mL) (71447-008-00)



BIO | MEDICAL



BIO | MEDICAL

MOUSSE MICELLAIRE
BioAcne
MICELLAR FOAM

Traitement topique de l'acné
Topical treatment of acne



Net Wt. 5.07 FL.OZ. (150 ml)

Ingredients (INCI): Aloe Barbadensis Leaf Juice*, Arctium Lappa Root Extract*, Urtica Dioica (Nettle) Extract*, Lavandula Angustifolia (Lavender) Flower Extract*, Propanediol, Coco-Glucoside, Glycerin, Salicylic Acid, Silver Citrate, Arginine, Magnolia Officinalis Bark Extract, Michelia Alba Flower Oil, Citrus Aurantifolia (Lime) Oil*, Lavandula Hybrid Oil*, Tea Tree Leaf Oil*, Citrus Aurantium Dulcis (Orange) Peel Oil (Expressed*), Sodium Gluconate, Levulinic Acid, Sodium Levulinate, Potassium Sorbate, Citric Acid, Aqua.

*Ingredients from Organic Farming. / *Ingrédients issus de l'agriculture biologique.
76% of the total ingredients are from organic farming / du total des ingrédients sont issus de l'agriculture biologique.
99% natural origin of total. / du total est d'origine naturelle.

COSMOS ORGANIC certified by Ecocert Greenlife according to COSMOS standard available at www.cosmos.ecocert.com
COSMOS ORGANIC certifié par Ecocert Greenlife selon le référentiel COSMOS disponible sur www.cosmos.ecocert.com

Fabricant/Manufacturer
Laboratoires Nelly De Vuyst
Division of Laboratoires Druide Inc.
Montreal (Qc), Canada

Distribué par/Distributed by
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Canada
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1 800.263.8888
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www.nellydevuyst.com



**Fabriqué au Canada
Made in Canada**

MICELLAR FOAM BioAcne 19211

Drug Facts

Active Ingredients Purpose
Salicylic Acid 0.5%.....Acne Treatment

Uses

Helps prevent new acne pimples from forming.

Warnings

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Stop use and ask a doctor if • you develop severe irritation, burning or itching of the skin • for more severe cases and/or if improvement is not apparent within 6 to 8 weeks.
• If you develop hives, swelling of eyes and mouth, blistering or difficulty breathing, get medical help right away.

Keep out of reach of children. If swallowed, call a Poison Control Centre or get medical help right away.

Directions:

- For New Users: Apply product to a small area once for to test if you are sensitive to this product.
- If no discomfort occurs, moisten skin with warm water.
- Dispense two full pumps of Purifying Foaming Wash into palm of hand, apply by gently massaging over the entire affected area, rinse thoroughly and pat dry.
- Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.
- If bothersome dryness, irritation or peeling occurs, reduce application to every other day.

Other Information:

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Inactive Ingredients: Aloe Barbadensis Leaf Juice*, Arctium Lappa Root Extract*, Urtica Dioica (Nettle) Extract*, Lavandula Angustifolia (Lavender) Flower Extract*, Propanediol, Coco-Glucoside, Glycerin, Silver Citrate, Arginine, Magnolia Officinalis Bark Extract, Michelia Alba Flower Oil, Citrus Aurantifolia (Lime) Oil*, Lavandula Hybrid Oil*, Tea Tree Leaf Oil*, Citrus Aurantium Dulcis (Orange) Peel Oil (Expressed*), Sodium Gluconate, Levulinic Acid, Sodium Levulinate, Potassium Sorbate, Citric Acid, Aqua.

Questions or Comments? Call 1.800.263.8888
Outside Canada or U.S.A. dial 514.333.8282 or visit www.nellydevuyst.com.

www.nellydevuyst.com



MOUSSE MICELLAIRE BioAcne

Information sur le produit

Ingrédients actifs Objet
Acide salicylique 0.5%...Traitement de l'acné

Indications: Aide à prévenir la formation de nouveaux boutons d'acné

Mises en garde:

Pour usage externe seulement.

Lorsque vous utilisez ce produit • Éviter tout contact avec les yeux; en cas de contact, rincer à grande eau • L'application concomitante d'autres produits topiques contre l'acné peut augmenter la sécheresse ou l'irritation de la peau. En cas d'irritation, utiliser un seul produit à la fois.

Cesser l'utilisation du produit et consulter un médecin • En cas d'irritation cutanée, sensation de brûlure ou démangeaisons sévères • Dans les cas d'acné les plus graves et/ou si aucune amélioration n'est visible après 6 à 8 semaines.

• En cas d'urticaire, de gonflement des yeux ou de la bouche, d'apparition de cloques ou de difficultés à respirer, obtenir une assistance médicale immédiate.

Garder hors de portée des enfants. En cas d'ingestion, appeler un centre antipoison ou obtenir une assistance médicale immédiate.

Mode d'emploi:

- Pour les nouveaux utilisateurs: appliquez le produit sur une petite zone une fois pour tester si vous êtes sensible à ce produit.
- Si vous ne sentez aucun inconfort, utilisez le matin et / ou le soir.
- Verser la mousse dans la paume de votre main, appliquer doucement sur la région affectée, rincer abondamment avec l'eau et sécher.
- Parce qu'un dessèchement excessif de la peau peut se produire, commencez par une application par jour, puis augmentez graduellement jusqu'à deux ou trois fois par jour si nécessaire ou selon les directives d'un médecin.
- Si une sécheresse gênante, une irritation ou un gommage se produit, réduire l'application tous les deux jours.

Autres renseignements: protéger le produit dans ce récipient contre la chaleur excessive et le soleil direct.

Questions ou Commentaires? Appeler 1.800.263.8888 Extérieur de Canada ou U.S.A. composer le 514.333.8282 ou visiter www.nellydevuyst.com.

NPN 80083013

NELLY DEVUYST MICELLAR FOAM BIOACNE

salicylic acid liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:71447-008

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ) | SALICYLIC ACID | 0.5 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| URTICA DIOICA LEAF (UNII: X6M0DRN46Q) | |
| LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M) | |
| WATER (UNII: 059QF0KO0R) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ARCTIUM LAPPA ROOT OIL (UNII: 55DGS3F5YG) | |
| COCO GLUCOSIDE (UNII: ICS790225B) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SILVER CITRATE (UNII: CKA421A1J7) | |
| ARGININE (UNII: 94ZLA3W45F) | |
| MAGNOLIA OFFICINALIS BARK (UNII: 5M609NV974) | |
| PROPANEDIOL (UNII: 5965N8W85T) | |
| MICHELIA ALBA LEAF OIL (UNII: 002RK9L1FN) | |
| LAVANDIN OIL (UNII: 9RES347CKG) | |
| CITRUS AURANTIUM FRUIT OIL (UNII: 59JDQ5VT0T) | |
| LIME OIL (UNII: UZH29XGA8G) | |
| TEA TREE OIL (UNII: VIF565UC2G) | |
| SODIUM GLUCONATE (UNII: R6Q3791S76) | |
| LEVULINIC ACID (UNII: RYX5QG61EI) | |
| SODIUM LEVULINATE (UNII: VK44E1MQU8) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71447-008-00 | 1 in 1 CARTON | 04/25/2018 | |
| 1 | | 150 mL 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 |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part333D | 04/25/2018 | |

Labeler - LABORATOIRES DRUIDE INC (245815014)**Registrant** - LABORATOIRES DRUIDE INC (245815014)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|----------------|---------------|----------------------------|
| 7774672 CANADA INC | | 203095039 | pack(71447-008) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|----------------|---------------|---|
| LABORATOIRES DRUIDE INC | | 2458 150 14 | manufacture(71447-008) , label(71447-008) |

Revised: 4/2018

LABORATOIRES DRUIDE INC