

NELLY DEVUYST PURIFYING BIOACNE- salicylic acid 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 PURIFYING GEL BIOACNE 150g

DRUG FACTS

Active Ingredient

Salicylic Acid 2%

Purpose

Acne Treatment

Uses

Helps keep skin clear of new acne pimples.

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

- Cleanse skin thoroughly before applying the product.
- For new users: apply product to a small area once a day for three days to test if you are sensitive to this product.
- If no discomfort occurs, cover the entire affected area with a thin layer.

- Start with one application daily, then gradually increase to two or three times daily, if needed.
- If dryness or peeling occurs, reduce application to once a day or every other day.

Other information

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

Inactive Ingredients

Aloe Barbadensis Leaf Juice*, Propanediol, Arctium Lappa Root Extract*, Urtica Dioica (Nettle) Extract*, Lavandula Angustifolia (Lavender) Flower Extract*, Glycerin, Zinc Oxide, Silver Citrate, 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*, Bentonite, Carrageenan, Sodium Gluconate, Levulinic Acid, Sodium Levulinate, Sodium Carboxymethyl Cellulose, Sodium Anisate, Sclerotium Gum, Xanthan Gum, Tocopherol, Citric Acid, Potassium Sorbate, 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 PURIFYING GEL BIOACNE 5.20.OZ. (150g)



BIO | MEDICAL

GEL PURIFIANT
BioAcne
PURIFYING GEL

Traitement topique de l'acné
Topical treatment of acne



AIRLESS

Net Wt. 5.20. OZ. (150 g)

NPN 80083027

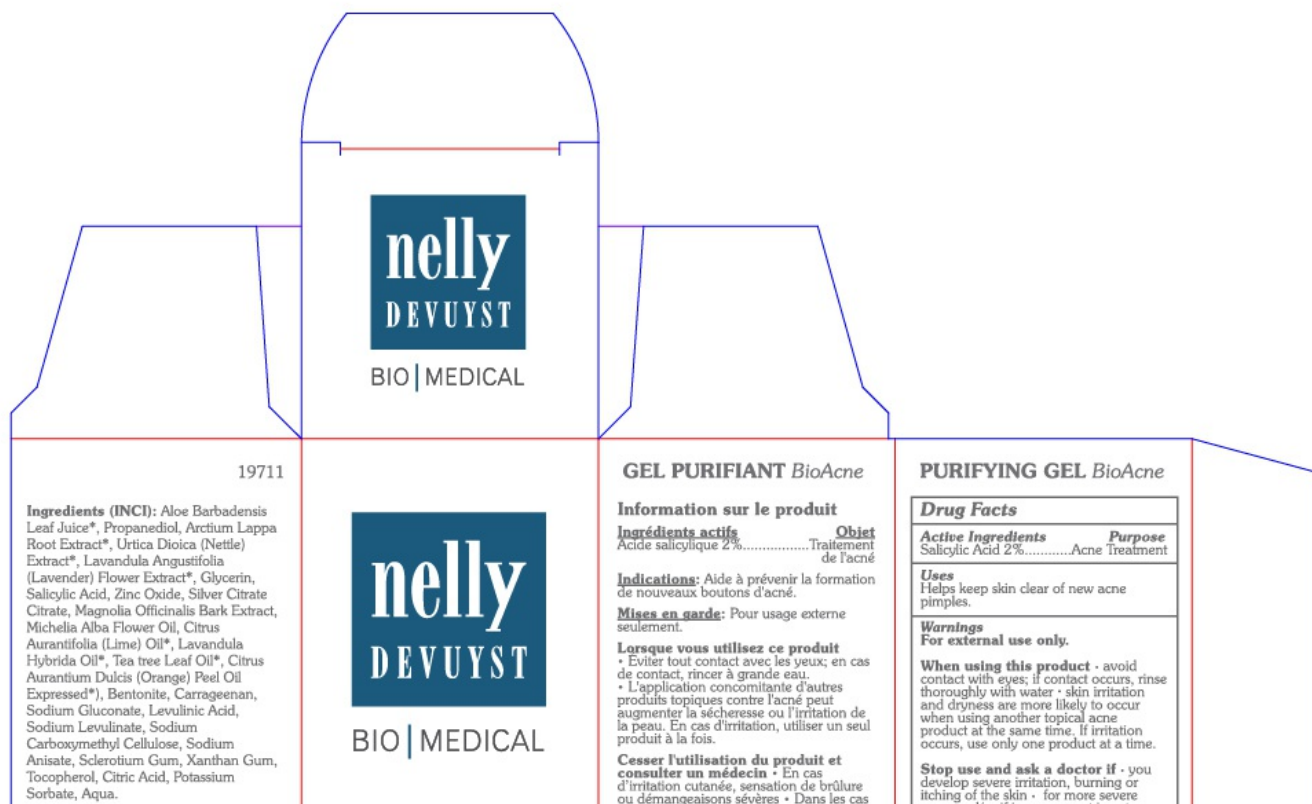
Drug Facts	
Active Ingredients Salicylic Acid 2%.....	Purpose Acne Treatment
Uses Helps keep skin clear of new acne pimples.	
Warnings For external use only. When using this product ■ avoid contact with eyes; if contact occurs, rinse thoroughly with water ■ skin irritation and dryness are more likely 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, call a Poison Control Centre or get medical help right away.	
Directions: ■ Cleanse skin thoroughly before applying the product ■ For new users: Apply product to a small area once a day for three days to test if you are sensitive to this product. ■ If no discomfort occurs, cover the entire affected area with a thin layer. ■ Start with one application daily, then gradually increase to two or three times daily, if needed. ■ If dryness or peeling occurs, reduce application to once a day or every other day.	
Other Information: Protect the product in this container from excessive heat and direct sun.	
Inactive Ingredients: Aloe Barbadosis Leaf Juice*, Propanediol, Arctium Lappa Root Extract*, Urtica Dioica (Nettle) Extract*, Lavandula Angustifolia (Lavender) Flower Extract*, Glycerin, Zinc Oxide, Silver Citrate, 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*, Bentonite, Carrageenan, Sodium Gluconate, Levulinic Acid, Sodium Levulinate, Sodium Carboxymethyl Cellulose, Sodium Anisate, Sclerotium Gum, Xanthan Gum, Tocopherol, Citric Acid, Potassium Sorbate, Aqua. *Certified Organic.	
Questions or Comments? Call 1.800.263.8888 Outside Canada or U.S.A. dial 514.333.8282 or visit www.nellydevuyst.com .	

Manufactured by/Fabriqué par
Laboratoires Nelly De Vuyst
Division of Laboratoires Druide Inc.
Montreal (Qc) H9R 1A8 Canada

Distributed by/Distribué par
7774672 Canada Inc. (Derme&co)
4930 chemin Bois Franc
St. Laurent (Qc) H4S 1A7 Canada
1 514.333.8282 / 1 800.263.8888 / info@derme.ca

www.nellydevuyst.com

Made in Canada/Fabriqué au Canada



*Ingredients from Organic Farming. / *Ingrédients issus de l'agriculture biologique. 52% of the total ingredients are from organic farming. / du total des ingrédients sont issus de l'agriculture biologique. 97% 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**
7774672 Canada Inc. (Derme&co)
St. Laurent (Qc) H4S 1A7 Canada
+1 514.333.8282
1 800.263.8888
info@derme.ca

www.nellydevuyst.com



**Fabriqué au Canada
Made in Canada**

GEL PURIFIANT BioAcne PURIFYING GEL

*Traitement topique de l'acné
Topical treatment of acne*



AIRLESS
Net Wt. 1.75. OZ. (50 g)

NPN 80063027

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 difficulté 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: • Bien nettoyer la peau avant d'appliquer le produit. • Pour les nouveaux utilisateurs: appliquer le produit sur une petite zone atteinte, une fois par jour pendant trois jours, pour savoir si vous êtes sensible à ce produit. • piquer une mince couche du produit sur toute la surface atteinte. • Commencer par une application par jour, puis augmenter graduellement la fréquence jusqu'à deux à trois applications par jour, au besoin. • En cas de sécheresse ou de desquamation de la peau, réduire la fréquence à une application par jour ou à une 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.

Les effets de l'application peuvent être apparents dans les 6 à 8 semaines.

• 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:

- Cleanse skin thoroughly before applying the product
- For new users: Apply product to a small area once a day for three days to test if you are sensitive to this product.
- If no discomfort occurs, cover the entire affected area with a thin layer.
- Start with one application daily, then gradually increase to two or three times daily, if needed.
- If dryness or peeling occurs, reduce application to once a day or every other day.

Other Information:

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

Inactive Ingredients: Aloe Barbadosensis Leaf Juice*, Propanediol, Arctium Lappa Root Extract*, Urtica Dioica (Nettle) Extract*, Lavandula Angustifolia (Lavender) Flower Extract*, Glycerin, Zinc Oxide, Silver Citrate, 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*), Bentonite, Carrageenan, Sodium Gluconate, Levulinic Acid, Sodium Levulinate, Sodium Carboxymethyl Cellulose, Sodium Anisate, Sclerotium Gum, Xanthan Gum, Tocopherol, Citric Acid, Potassium Sorbate, Aqua.
*Certified Organic.

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



NELLY DEVUYST PURIFYING BIOACNE

salicylic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71447-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

MICHELIA ALBA LEAF OIL (UNII: 002RK9L1FN)
SILVER CITRATE (UNII: CKA421A1J7)
MAGNOLIA OFFICINALIS BARK (UNII: 5M609NV974)
LAVANDIN OIL (UNII: 9RES347CKG)
CITRUS AURANTIUM FRUIT OIL (UNII: 59JDQ5VT0T)
BENTONITE (UNII: A3N5ZCN45C)
CARRAGEENAN (UNII: 5C69YCD2YJ)
GLYCERIN (UNII: PDC6A3C0OX)
SODIUM GLUCONATE (UNII: R6Q3791S76)
LEVULINIC ACID (UNII: RYX5QG61EJ)
SODIUM LEVULINATE (UNII: VK44E1MQU8)
PROPANEDIOL (UNII: 5965N8W85T)
URTICA DIOICA LEAF (UNII: X6M0DRN46Q)
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)
SODIUM ANISATE (UNII: F9WFJ28MV9)
BETASIZOFIRAN (UNII: 2X51AD1X3T)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
WATER (UNII: 059QF0K00R)
XANTHAN GUM (UNII: TTV12P4NEE)
TOCOPHEROL (UNII: R0ZB2556P8)
LIME OIL (UNII: UZH29XGA8G)
TEA TREE OIL (UNII: VIF565UC2G)
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)
ZINC OXIDE (UNII: SOI2LOH54Z)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
ARCTIUM LAPPA ROOT (UNII: 597E9BIBZ3)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71447-004-01	150 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	05/26/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	05/26/2018	

Labeler - LABORATOIRES DRUIDE INC (245815014)

Registrant - LABORATOIRES DRUIDE INC (245815014)

Establishment

Name	Address	ID/FEI	Business Operations
7774672 CANADA IINC		203095039	pack(71447-004)

Establishment

Name	Address	ID/FEI	Business Operations
LABORATOIRES DRUIDE INC		2458 150 14	manufacture(71447-004) , label(71447-004)

Revised: 5/2018

LABORATOIRES DRUIDE INC