

**NELLY DEVUYST SERUM 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.*

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**NELLY DEVUYST SERUM BIOACNE 100mL**

***DRUG FACTS***

***Active Ingredients***

Salicylic Acid 2%

***Purpose***

Acne Treatment

***Uses***

Penetrates pores to control or reduce 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**

▪ 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**

Thymus Vulgaris (Thyme) Extract\*, Alcohol, Arctium Lappa Root Extract\*, Urtica Dioica (Nettle) Extract\*, Lavandula Angustifolia (Lavender) Flower Extract\*, Propanediol, 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\*, Arginine, 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.nellydevuyt.com](http://www.nellydevuyt.com)

**Distributed By**

7774672 Canada Inc (Derme & Co)  
 4980 Chemin Bois Franc  
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[www.nellydevuyt.com](http://www.nellydevuyt.com)  
 Made in Canada

**NELLY DEVUYST SERUM BIOACNE 3.30 FL.OZ (100mL) (71447-009-01)**



BIO | MEDICAL



SÉRUM-SERUM  
**BioAcne**

Traitement topique de l'acné  
 Topical treatment of acne

Net Wt. 3.30 FL.OZ. (100 ml)

NPN 80083018

19432	
<b>Drug Facts</b>	
<b>Active Ingredients</b> Salicylic Acid 2%	<b>Purpose</b> Acne Treatment
<b>Uses</b> Penetrates pores to control (reduce) acne pimples.	
<b>Warnings</b> 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.	
<b>Directions:</b> • 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.	
<b>Other Information:</b> Protect the product in this container from excessive heat and direct sun.	
<b>Inactive Ingredients:</b> Thymus Vulgaris (Thyme) Extract*, Alcohol*, Arctium Lappa Root Extract*, Urtica Dioica (Nettle) Extract*, Lavandula Angustifolia (Lavender) Flower Extract*, Propanediol, 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*, Arginine, Levulinic Acid, Sodium Levulinate, Potassium Sorbate, Citric Acid, Aqua. *Certified Organic	
<b>Questions or Comments?</b> Call 1.800.263.8888 Outside Canada or U.S.A. dial 514.333.8282 or visit <a href="http://www.nellydevuyt.com">www.nellydevuyt.com</a> .	
<b>Manufactured by/Fabriqué par</b> Laboratoires Nelly De Vuyst Division of Laboratoires Duende Inc. Montreal (Qc) H9R 1A8 Canada	<b>Distributed by/Distribué par</b> 7774672 Canada Inc. (Derme&Co) 4920 chemin Bois Franc, St. Laurent (Qc) H4S 1A7 Canada +1 514.333.8282 / 1 800.263.8888 info@derme.ca / <a href="http://www.nellydevuyt.com">www.nellydevuyt.com</a>
<b>Made in Canada/Fabriqué au Canada</b>	 8 29852 19432 19

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DEVUYST

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SÉRUM-SERUM  
BioAcne

Traitement topique de l'acné  
Topical treatment of acne



AIRLESS

Net Wt. 0.5 FL.OZ. (15 ml)

NPN 80083018

SÉRUM BioAcne 19431

**Drug Facts**

**Active Ingredients Purpose**  
Salicylic Acid 2%..... Acne Treatment

**Uses**  
Penetrates pores to control (reduce) acne pimples.

**Warnings**  
For external use only.

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**Questions or Comments?**  
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www.nellydevuyst.com

**Information sur le produit**

**Ingrédients actifs** **Objet**  
Acide salicylique 2%..... Traitement de l'acné

**Indications:** Pénètre dans les pores de la peau pour contrôler (réduire) les boutons d'acné.

**Miss 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 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. - Si vous ne ressentez aucun inconfort, appliquer 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.

**Ingredients (INCI):** Thymus Vulgaris (Thyme) Extract\*, Alcohol\*\*, Arctium Lappa Root Extract\*, Urtica Dioica (Nettle) Extract\*, Lavandula Angustifolia (Lavender) Flower Extract\*, Propandiol, Salicylic Acid, 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\*, Arginine, Glycerin, Levulinic Acid, Sodium Levulinate, Potassium Sorbate, Citric Acid, Aqua.

\*\*Made using organic ingredients / \*\*Transmitted à partir d'ingrédients biologiques. \*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, 98% 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

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info@derme.ca  
www.nellydevuyst.com



**Fabriqué au Canada  
Made in Canada**



NELLY DEVUYST SERUM BIOACNE

salicylic acid liquid

Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71447-009
<b>Route of Administration</b>	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 mL

### Inactive Ingredients

Ingredient Name	Strength
LEVULINIC ACID (UNII: RYX5QG61EI)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM LEVULINATE (UNII: VK44E1MQU8)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROPANEDIOL (UNII: 5965N8W85T)	
ARCTIUM LAPPA ROOT (UNII: 597E9B13Z3)	
URTICA DIOICA LEAF (UNII: X6M0DRN46Q)	
WATER (UNII: 059QF0K00R)	
THYMUS VULGARIS LEAF (UNII: GRX3499643)	
LAVANDIN OIL (UNII: 9RES347CKG)	
ALCOHOL (UNII: 3K9958V90M)	
LIME OIL (UNII: UZH29XGA8G)	
CITRUS AURANTIUM FRUIT OIL (UNII: 59JDQ5VT0T)	
ARGININE (UNII: 94ZLA3W45F)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
TEA TREE OIL (UNII: VIF565UC2G)	
SILVER CITRATE (UNII: CKA421A1J7)	
MAGNOLIA OFFICINALIS BARK (UNII: 5M609NV974)	
MICHELIA ALBA LEAF OIL (UNII: 002RK9L1FN)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71447-009-01	1 in 1 CARTON	05/26/2018	
1		100 mL in 1 BOTTLE, GLASS; 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	05/26/2018	

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

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

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
7774672 CANADA INC		203095039	pack(71447-009)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LABORATOIRES DRUIDE INC		2458 150 14	manufacture(71447-009) , label(71447-009)

Revised: 5/2018

LABORATOIRES DRUIDE INC