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.

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.nellydevuyst.com

Distributed By

7774672 Canada Inc (Derme & Co) 4980 Chemin Bois Franc St. Laurent, QC H4S 1A7 Canada

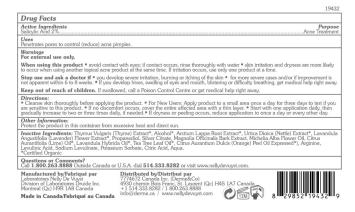
+1514-333-8282, +1800-263-8888

www.nellydevuyst.com

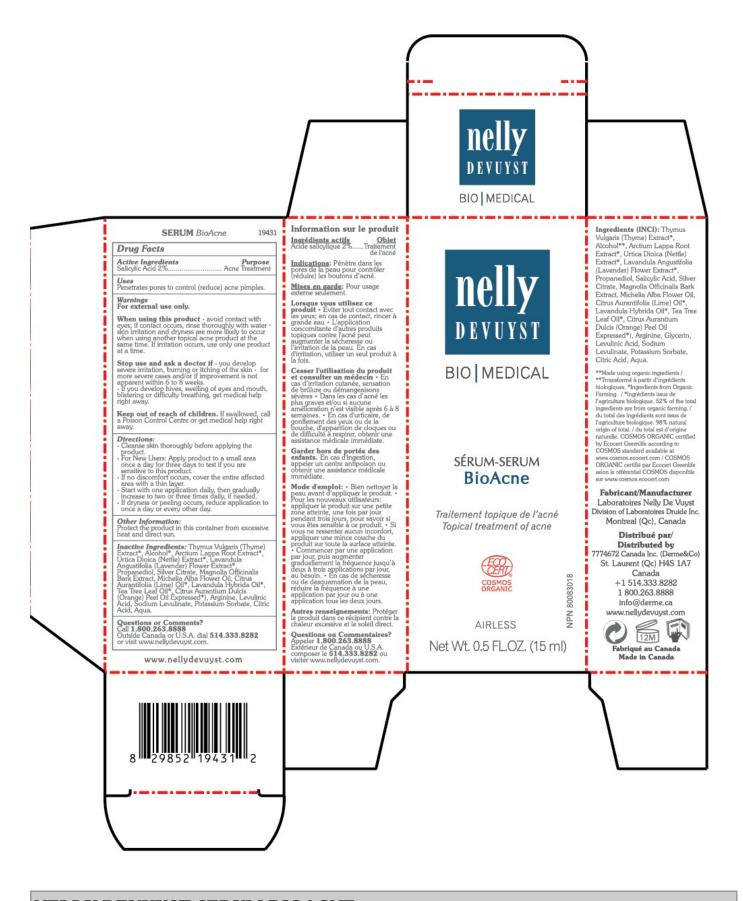
Made in Canada

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





10/12/2



NELLY DEVUYST SERUM BIOACNE

salicylic acid liquid

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71447-009 |
|-------------------------|----------------|--------------------|---------------|
| 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 mL | | |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| LEVULINIC ACID (UNII: RYX5QG61EI) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| SODIUM LEVULINATE (UNII: VK44E1MQU8) | |
| CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP) | |
| PROPANEDIOL (UNII: 5965N8W85T) | |
| ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3) | |
| URTICA DIO ICA LEAF (UNII: X6M0 DRN46Q) | |
| WATER (UNII: 059QF0KO0R) | |
| THYMUS VULGARIS LEAF (UNII: GRX3499643) | |
| LAVANDIN O IL (UNII: 9 RES 347 CKG) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| LIME OIL (UNII: UZH29 XGA8 G) | |
| CITRUS AURANTIUM FRUIT O IL (UNII: 59JDQ5VT0T) | |
| ARGININE (UNII: 94ZLA3W45F) | |
| LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19 AH1RAF4M) | |
| TEA TREE O IL (UNII: VIF565UC2G) | |
| SILVER CITRATE (UNII: CKA421A1J7) | |
| MAGNOLIA OFFICINALIS BARK (UNII: 5M609NV974) | |
| MICHELIA ALBA LEAF O IL (UNII: 002RK9L1FN) | |

| Packaging | | | |
|------------------|--|-------------------------|-----------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:71447-009- | 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 - LABORATORES DRUIDE INC (245815014)

Registrant - LABORATOIRES DRUIDE INC (245815014)

| Establishment | | | |
|--------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| 7774672 CANADA INC | | 203095039 | pack(71447-009) |

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

Revised: 5/2018 LABORATOIRES DRUIDE INC