

**NELLY DEVUYST ORGANIC SUNSCREEN NATURAL PROTECTION BROAD
SPECTRUM SPF30- titanium dioxide, zinc oxide cream
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 ORGANIC CREAM SUNSCREEN NATURAL PROTECTION BROAD
SPECTRUM SPF30**

Active Ingredients

Titanium Dioxide 6.5%
Zinc Oxide 6.3%

Purpose

Sunscreen

Uses

▪ Helps prevent sunburn. ▪ If used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only

Do not use

on damaged or broken skin.

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 liberally and evenly 15 minutes before sun exposure ▪ Reapply ▪ After 80 minutes of swimming or sweating ▪ Immediately after towel drying ▪ At least every 2 hours ▪ **Sun Protection Measures** ▪ Spending

time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: ■ Limit time in the sun, especially from 10 a.m. - 2 p.m. ■ Wear long-sleeved shirts, pants, hats, and sunglasses ■ Use a water-resistant sunscreen if swimming or sweating.

Other Information

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

Inactive Ingredients

ALOE BARBADENSIS LEAF JUICE*, ASPALATHUS LINERIS (ROOIBOS) EXTRACT*, ACMELLA OLERACEA EXTRACT, ASCORBYL GLUCOSIDE, AQUA, ALCOHOL, ALUMINA, BENTONITE, BENZYL ALCOHOL, COCOS NUCIFERA (COCONUT) OIL*, CAMEL*, CAPRYLIC/CAPRIC TRIGLYCERIDE, COCO-CAPRYLATE, CITRIC ACID, GLYCERIN, HELIANTHUS ANUUS (SUNFLOWER) OIL*, ISOSTEARIC ACID, KAOLIN, LECITHIN, PROPANEDIOL, POLYHYDROXYSTEARIC ACID, POLYGLYCERYL-3 POLYRICINOLEATE, POTASSIUM SORBATE, SODIUM STEAROYL GLUTAMATE, SODIUM HYALURONATE, SODIUM GLUCONATE, STEARIC ACID, SALICYLIC ACID, SORBIC ACID, TOCOPHEROL, XANTHAN GUM.

*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 ORGANIC CREAM SUNSCREEN NATURAL PROTECTION BROAD SPECTRUM SPF30 120g (71447-002-01)

	<p>Natural Protection: Apply a dot of cream every 2 inches on the skin. Massage well to ensure uniform application. 19601</p>								
<p>BIO ORGANIC</p>	<table border="1"> <thead> <tr> <th colspan="2">Drug Facts</th> </tr> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Titanium Dioxide.....6.5%</td> <td>Sunscreen</td> </tr> <tr> <td>Zinc Oxide.....6.3%</td> <td>Sunscreen</td> </tr> </tbody> </table>	Drug Facts		Active Ingredients	Purpose	Titanium Dioxide.....6.5%	Sunscreen	Zinc Oxide.....6.3%	Sunscreen
Drug Facts									
Active Ingredients	Purpose								
Titanium Dioxide.....6.5%	Sunscreen								
Zinc Oxide.....6.3%	Sunscreen								
<p>Cream SUNSCREEN</p>	<p>Uses ■ helps prevent sunburn. ■ if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by sun.</p>								
<p>Natural Protection</p>	<p>Warnings For external use only. ■ Do not use ■ on damaged or broken skin. When using this product ■ keep out of eyes. Rinse with water to remove. Stop use and ask a doctor ■ if rash occurs</p>								
<p>Broad Spectrum SPF30</p>	<p>Directions ■ apply liberally and evenly 15 minutes before sun exposure ■ children under 6 months of age: Ask a doctor ■ reapply: ■ after 80 minutes of swimming or sweating ■ immediately after towel drying ■ at least every 2 hours ■ Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: ■ limit time in the sun, especially from 10a.m - 2p.m ■ wear long-sleeved shirts, pants, hats and sunglasses ■ reapply at least every 2 hours ■ use a water-resistant sunscreen if swimming or sweating.</p>								
<p>AIRLESS</p>	<p>Other information Protect the product in this container from excessive heat and direct sun.</p>								
<p>NET WT. 4.23 OZ. (120 g)</p>	<p>Inactive ingredients Aloe Barbadensis Leaf Juice*, Aspalathus Lineris (Rooibos) Extract*, Acemella Oleracea Extract, Ascorbyl Glucoside, Aqua, Alcohol, Alumina, Bentonite, Benzyl Alcohol, Cocos Nucifera (Coconut) Oil*, Caramel*, Caprylic/Capric Triglyceride, Coco-Caprylate, Citric Acid, Glycerin, Helianthus Anuus (Sunflower) Oil*, Isostearic Acid, Kaolin, Lecithin, Propanediol, Polyhydroxystearic Acid, Polyglyceryl-3 Polyricinoleate, Potassium Sorbate, Sodium Stearoyl Glutamate, Sodium Hyaluronate, Sodium Gluconate, Stearic Acid, Salicylic Acid, Sorbic Acid, Tocopherol, Xanthan Gum. *Certified Organic</p>								
	<p>Questions or Comments? Call 1.800.263.8888 Outside Canada or U.S dial 514.333.8282 or visit www.nellydevuyst.com</p>								
	<table border="0"> <tr> <td> <p>Manufactured by Laboratoires Nelly De Vuyst Division of Laboratoires Druide Inc. Pointe-Claire, QC H9R 1A8 Canada Made in Canada</p> </td> <td> <p>Distributed by 7774672 CANADA INC. DBA Derme&co St. Laurent (Qc) H4S 1A7 Canada</p> </td> </tr> </table>	<p>Manufactured by Laboratoires Nelly De Vuyst Division of Laboratoires Druide Inc. Pointe-Claire, QC H9R 1A8 Canada Made in Canada</p>	<p>Distributed by 7774672 CANADA INC. DBA Derme&co St. Laurent (Qc) H4S 1A7 Canada</p>						
<p>Manufactured by Laboratoires Nelly De Vuyst Division of Laboratoires Druide Inc. Pointe-Claire, QC H9R 1A8 Canada Made in Canada</p>	<p>Distributed by 7774672 CANADA INC. DBA Derme&co St. Laurent (Qc) H4S 1A7 Canada</p>								



NELLY DEVUYST ORGANIC SUNSCREEN NATURAL PROTECTION BROAD SPECTRUM SPF30

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71447-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	65 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	63 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBIC ACID (UNII: X045WJ989B)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PROPANEDIOL (UNII: 5965N8W85T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU)	
ACMELLA OLERACEA FLOWERING TOP (UNII: 1O11RD9U53)	
ALCOHOL (UNII: 3K9958V90M)	
BENTONITE (UNII: A3N5ZCN45C)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
ALUMINUM OXIDE (UNII: LM26O6933)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARAMEL (UNII: T9D99G2B1R)	
COCONUT OIL (UNII: Q9L0O73W7L)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
WATER (UNII: 059QF0KO0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
KAOLIN (UNII: 24H4NWX5CO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71447-002-01	120 g in 1 TUBE; Type 0: Not a Combination Product	06/12/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/12/2017	

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

Name	Address	ID/FEI	Business Operations
7774672 CANADA INC		203095039	pack(71447-002)

Establishment

Name	Address	ID/FEI	Business Operations
LABORATOIRES DRUIDE INC		245815014	manufacture(71447-002)

Revised: 6/2017

LABORATOIRES DRUIDE INC