

**BIOMI ACTION DE GALA MINERAL SUNSCREEN 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.*

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**BIOMI ACTION DE GALA SFP 30 MINERAL SUNSCREEN 50 mL**

***DRUG FACTS***

***Active Ingredients***

Titanium Dioxide 2.0%

Zinc Oxide 18.4%

***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**

**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***

C10-18 Triglycerides, Sodium Citrate, Panax Ginseng Extract\*, Tocopherol, Propanediol, Potassium Sorbate, Sodium Stearoyl Glutamate, Hyaluronate Sodium, Aloe Barbadensis Leaf Juice\*, Coco-Caprylate, Alumina, Glycerin, Stearic Acid, Xanthan Gum, Lecithin, Polyhydroxystearic Acid, Polyglyceryl-3 Polyricinoleate, Salicylic Acid, Benzyl Alcohol, Isostearic Acid, Sorbic Acid, Cetyl Alcohol, Caprylic/Capric/ Linoleic Triglyceride, Glyceryl Stearate.

\*Certified Organic.

### **Questions or Comments?**

**1-800-463-5566**

Outside Canada or the United States dial **+1 418-650-0303** or visit [www.dectro.com](http://www.dectro.com)

**BIOMI ACTION DE GALA SFP 30 MINERAL SUNSCREEN 50 mL (NDC 73626-050-00)**



<b>BIOMI ACTION DE GALA MINERAL SUNSCREEN SPF30</b>			
titanium dioxide, zinc oxide cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71447-050

**Route of Administration** TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2 g in 100 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	18.4 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>CAPRYLIC/CAPRIC/LINOLEIC TRIGLYCERIDE</b> (UNII: U73D397055)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>C10-18 TRIGLYCERIDES</b> (UNII: 43AGM4PHPI)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>PANAX GINSENG ROOT OIL</b> (UNII: P9T4K47OM0)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>SODIUM STEAROYL GLUTAMATE</b> (UNII: 65A9F4P024)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>COCO-CAPRYLATE</b> (UNII: 4828G836N6)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>LECITHIN, SUNFLOWER</b> (UNII: 834K0WOS5G)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>POLYGLYCERYL-3 RICINOLEATE</b> (UNII: MZQ63P0N0W)	
<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>ISOSTEARIC ACID</b> (UNII: X33R8U0062)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71447-050-01	1 in 1 BOX	03/01/2020	
1	NDC:71447-050-00	50 mL in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part352	03/01/2020	
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**Labeler** - LABORATOIRES DRUIDE INC (245815014)

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

**Establishment**

Name	Address	ID/FEI	Business Operations
LABORATOIRES DRUIDE INC		245815014	manufacture(71447-050)

Revised: 3/2021

LABORATOIRES DRUIDE INC