

## **BION 8 FLOZ PURE MINERAL SUNSCREEN SPF 30- sunscreen emulsion CA-Botana International INC**

### **Bion 8 Oz Pure Mineral Sunscreen**

#### **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 product is swallowed, get medical help or contact a poison control center right away.

#### **Dosage & Administration**

Helps prevent sunburn. If used as directed with other sun protection measured decreases the risk of skin cancer and early skin aging caused by the sun. Apply liberally 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply: at least 2 hours. Children under 6 months: Ask a doctor. Sun protection measurements. 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 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-sleeve shirts, pants, hats, and sunglasses. Protect this product from excessive heat and direct sun

#### **Inactive Ingredients**

Hyaluronic Acid, Cetearyl Alcohol, Glycerin, Horse Chestnut, Vanilla Planifolia Fruit, Xanthan Gum, Hydrated Silica, Alkyl (C12-15) Benzoate, Phenoxyethanol, Triethoxycaprylylsilane, Potassium Sorbate, Beeswax, Ascorbyl Palmitate, Stearic Acid, Ceteareth-15, Macadamia Ternifolia Seed oil, Mica, Isomalt, Green tea leaf. Polyhydroxystearic acid stearate, Olea Europaea (Olive) leaf powder, Vitis Vinifera (Grape) seed oil, Ascorbic Acid, Propanediol, .Alpha.-Tocopherol Acetate, D, Ethylhexylglycerin, Lecithin, Soybean, Caprylic/Capric Triglyceride, Tocopherol, Aloe, Decyl Oleate, Ethylhexyl Palmitate, Water, Shea Butter, Rosmarinus Officinalis (Rosemary) Leaf powder, Panthenol, Phosphatidylcholine, Soybean, Citric Acid, Orange oil, Niacinamide, Stearyl Alcohol, Centella Asiatica, Coco-Caprilate/Caprinate, Phytate Sodium.

#### **Active ingredients**

Zinc Oxide 19% Sunscreen

#### **Warning**

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 product is swallowed, get medical help or contact a

poison control center right away.

EDIT

### **Keep out of reach of Children**

Keep out of reach of children section [OTC - KEEP OUT OF REACH OF CHILDREN SECTION] For external use only.

Avoid contact with eyes.

Keep out of reach of children.

Do not apply to open wounds.

STOP USE AND ask a doctor if condition worsens or symptoms persist for more than seven days, discontinue use of the product.

### **Indications of usage**

Helps prevent sunburn. If used as directed with other sun protection measured decreases the risk of skin cancer and early skin aging caused by the sun. Apply liberally 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply: at least 2 hours. Children under 6 months: Ask a doctor. Sun protection measurements. 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 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-sleeve shirts, pants, hats, and sunglasses. Protect this product from excessive heat and direct sun

### **Purpose**

Sunscreen

### **Package Label**

FOR PROFESSIONAL USE ONLY  
NOT FOR RESALE

**BION**  
skincare  
products

PURE MINERAL  
SUNSCREEN

BROAD SPECTRUM SPF 30

8 FL OZ | 240 ML

NDC# 35192-061-15

Drug Facts	
<b>Active Ingredients:</b> Zinc Oxide 19%	<b>Purpose:</b> Sunscreen
<b>Warnings</b> <ul style="list-style-type: none"><li>• For External Use only.</li><li>• Do not use on damaged or broken skin.</li><li>• When using this product keep out of eyes. Rinse with water to remove.</li><li>• Stop use and ask a doctor if rash occurs.</li><li>• Keep out of reach of children. If product is swallowed, get medical help or contact Poison Control Center right away.</li></ul>	
<b>Directions for use</b> <ul style="list-style-type: none"><li>• Apply evenly to skin 15 minutes before sun exposure.</li><li>• Reapply<ul style="list-style-type: none"><li>• At least every 2 hours</li><li>• Use a water resistant sunscreen if swimming or sweating</li></ul></li><li>• <b>Sun Protection Measures.</b> 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:<ul style="list-style-type: none"><li>• limit time in the sun, especially from 10 a.m. - 2 p.m.</li><li>• wear long-sleeved shirts, pants, hats, and sunglasses</li></ul></li><li>• Children under 6 months of age: Ask a doctor.</li></ul>	
<b>Inactive ingredients:</b> Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Aloe barbadensis Extract, Ascorbyl Palmirate, Beeswax, Butyrospermum Parkii (Shea) Butter, Camellia Sinensis (Green Tea) Leaf Extract, C12-15 Alkyl Benzoate, Centella Asiatica (Gotu Kola) Extract, Cetearyl Alcohol, Ceteareth-15, Citrus Aurantium Dulcis (Orange) Fruit Oil, Coco-Caprylate/Caprate, Decyl Oleate, Ethylhexylglycerin, Ethylhexyl Palmirate, Equisetum Arvense (Horseail) Extract, Glycerin, Hyaluronic Acid, Isomalt, Lecithin, Macadamia Ternifolia Seed Oil, Mica, Niacinamide, Olea Europaea (Olive) Leaf Extract, Oxy CA, Panthenol, Phenoxylethanol, Phosphatidylcholine, Polyhydroxystearic Acid, Potassium Sorbate, Propanediol, Rosmarinus Officinalis (Rosemary) Extract, Sodium Phytate, Stearyl Alcohol, Silica, Tocopheryl Acetate, Zano20, Vanilla Planifolia Fruit Extract, Vitis Vinifera (grape) Fruit Cell Extract, Water/Aqua, Xanthan Gum	
<b>Other information:</b> Protect the product in this container from excessive heat and direct sun.	
<b>Questions or Comments?</b> Call toll-free 877-715-2466	

**BION 8 FLOZ PURE MINERAL SUNSCREEN SPF 30**

sunscreen emulsion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35192-061
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	19 g in 19 g
Inactive Ingredients			
Ingredient Name			Strength
HORSE CHESTNUT (UNII: 3C18L6RJAZ)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
OLEA EUROPAEA (OLIVE) LEAF POWDER (UNII: MJ95C3OH47)			
WATER (UNII: 059QF0KO0R)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)			
XANTHAN GUM (UNII: TTV12P4NEE)			

CETEARETH-15 (UNII: 867H4YOZ8Z)	
ORANGE OIL (UNII: AKN3KSD11B)	
NIACINAMIDE (UNII: 25X51I8RD4)	
MACADAMIA TERNIFOLIA SEED OIL (UNII: 515610SU8C)	
ISOMALT (UNII: S870P55O2W)	
VITIS VINIFERA (GRAPE) SEED OIL (UNII: 930MLC8XGG)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
PROPANEDIOL (UNII: 5965N8W85T)	
PANTHENOL (UNII: WW9CM0O67Z)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
VANILLA PLANIFOLIA FRUIT (UNII: Q74T35078H)	
HYALURONIC ACID (UNII: S270N0TRQY)	
SHEA BUTTER (UNII: K49155WL9Y)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
DECYL OLEATE (UNII: ZGR06DO97T)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
BEESWAX (UNII: 2ZA36H0S2V)	
MICA (UNII: V8A1AW0880)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
CITRIC ACID (UNII: 2968PHW8QP)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
ROSMARINUS OFFICINALIS (ROSEMARY) LEAF POWDER (UNII: IJ67X351P9)	
EQUISETUM ARVENSE LEAF POWDER (UNII: 1L0VKZ185E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALOE (UNII: V5VD430YW9)	
SOYBEAN PHOSPHATIDYLCHOLINE (UNII: 1T6N4D9YV6)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
PHYTATE SODIUM (UNII: 88496G1ERL)	

### Product Characteristics

Color	white (Yellowish)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-061-15	240 g in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2025	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/08/2025	

**Labeler -** CA-Botana International INC (106276728)

## Establishment

Name	Address	ID/FEI	Business Operations
CA-Botana International INC		106276728	manufacture(35192-061)

Revised: 5/2025

CA-Botana International INC