

BION 4 FLOZ PURE MINERAL SUNSCREEN SPF 30- sunscreen emulsion CA-Botana International INC

BION 4FLOZ Pure Mineral Sunscreen SPF 30

Warning & Precautions

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, Cetareth-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 Ingredient

Zinc Oxide 19 %

Purpose

Sunscreen, helps prevent sunburn

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

Warnings

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Indications & 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

BION

skincare
products

pure mineral

sunscreen

BROAD SPECTRUM SPF 30

4 FL OZ | 120 ML

Drug Facts

Active Ingredients:
Zinc Oxide 19%

Purpose:
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 Poison Control Center right away.

Directions for use

- Apply evenly to skin 15 minutes before sun exposure.
- Reapply
 - At least every 2 hours
 - Use a water resistant sunscreen if swimming or sweating
- **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
- Children under 6 months of age: Ask a doctor.

Inactive Ingredients: Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Aloe Barbadosensis Extract, Ascorbyl Palmitate, 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 Palmitate, Equisetum Arvense (Horsefall) Extract, Glycerin, Hyaluronic Acid, Isomalt, Lecithin, Macadamia Ternifolia Seed Oil, Mica, Niacinamide, Olea Europaea (Olive) Leaf Extract, Oxy CA, Panthenol, Phenoxethanol, Phosphatidylcholine, Polyhydroxystearic Acid, Potassium Sorbate, Propanediol, Rosmarinus Officinalis (Rosemary) Extract, Sodium Phylate, Stearyl Alcohol, Silica, Tocopheryl Acetate, Zano 20, Vanilla Planifolia Fruit Extract, Vitis Vinifera (Grape) Fruit Cell Extract, Water/Aqua, Xanthan Gum

Other information:

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

Questions or Comments?

Call toll-free 877-715-2466

NDC# 35192-060-13

BION 4 FLOZ PURE MINERAL SUNSCREEN SPF 30

sunscreen emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35192-060
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
BEE SWAX (UNII: 2ZA36H0S2V)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
SHEA BUTTER (UNII: K49155WL9Y)	
ROSMARINUS OFFICINALIS (ROSEMARY) LEAF POWDER (UNII: IJ67X351P9)	

PHOSPHATIDYLCHOLINE, SOYBEAN (UNII: 1T6N4D9YV6)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
HYALURONIC ACID (UNII: S270N0TRQY)	
GLYCERIN (UNII: PDC6A3C0OX)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EQUISETUM ARVENSE LEAF POWDER (UNII: 1LOVKZ185E)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SOYBEAN LECITHIN (UNII: 1DI56QDM62)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
TOCOPHEROL (UNII: R0ZB2556P8)	
DECYL OLEATE (UNII: ZGR06DO97T)	
CITRIC ACID (UNII: 2968PHW8QP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ISOMALT (UNII: S870P55O2W)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETEARETH-15 (UNII: 867H4YOZ8Z)	
MICA (UNII: V8A1AW0880)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PANTHENOL (UNII: WW9CM0O67Z)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
MACADAMIA TERNIFOLIA SEED OIL (UNII: 515610SU8C)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	
VANILLA PLANIFOLIA FRUIT (UNII: Q74T35078H)	
OLEA EUROPAEA (OLIVE) LEAF POWDER (UNII: MJ95C3OH47)	
VITIS VINIFERA (GRAPE) SEED OIL (UNII: 930MLC8XGG)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
PROPANEDIOL (UNII: 5965N8W85T)	
ORANGE OIL (UNII: AKN3KSD11B)	
ALOE (UNII: V5VD430YW9)	

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:35192-060-13	120 g in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/09/2025	

Labeler - CA-Botana International INC (106276728)

Establishment

Name	Address	ID/FEI	Business Operations
CA-Botana International INC		106276728	manufacture(35192-060)

Revised: 5/2025

CA-Botana International INC