

BION PURE MINERAL SUNSCREEN- sunscreen lotion

CA Botana International INC

Bion Pure Mineral Sunscreen SPF 30

Warning and 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 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 every 2 hours. Children under 6 months: Ask a doctor. Sun protection measurments: Spending in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with broad spectrumSPF 15 or higher and other sun protection measures including: limit time in the sun, specially from 10:00 am to 2:00 pm Wear long sleeve shirts, pants, hats, and sun glasses. Protect this product from excessive heat and direct sun

Keep out of reach of children

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 symptions persist for more than seven days, discontinue use of the product

Purpose section

Sunscreen, helps prevent sunburn

Active Ingredient

Zinc Oxide 19%

Warning

Keep out of reach of children. If product is swallowed, get medical help or contact poison control center right away

Indication of usage

Keep out of reach of children. If product is swallowed, get medical help or contact

poison control center right away

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/Caprates, Phytate Sodium.

Package Label



NDC# 35192-058-14	
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 Parvifolii (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 (Horsetail) Extract, Glycerin, Hyaluronic Acid, Isomalt, Lecithin, Macadamia Ternifolia Seed Oil, Mica, Niacinamide, Olea Europaea (Olive) Leaf Extract, Oxy CA, Panthenol, Phenoxyethanol, Phosphatidylcholine, Polyhydroxystearic Acid, Potassium Sorbate, Propanediol, Rosmarinus Officinalis (Rosemary) Extract, Sodium Phytate, Stearyl Alcohol, Silica, Tocopheryl Acetate, Zinc Oxide, 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	

BION PURE MINERAL SUNSCREEN

sunscreen lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35192-058
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	19 g in 19 g
Inactive Ingredients		
Ingredient Name	Strength	
HYALURONIC ACID (UNII: S270N0TRQY)		
CETEARYL ALCOHOL (UNII: 2DMT128M1S)		
PHYTATE SODIUM (UNII: 88496G1ERL)		
GLYCERIN (UNII: PDC6A3C0OX)		
HORSE CHESTNUT (UNII: 3C18L6RJAZ)		
VANILLA PLANIFOLIA FRUIT (UNII: Q74T35078H)		
XANTHAN GUM (UNII: TTV12P4NEE)		
HYDRATED SILICA (UNII: Y6O7T4G8P9)		
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)		
EQUISETUM ARVENSE LEAF POWDER (UNII: 1L0VKZ185E)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
BEESWAX (UNII: 2ZA36H0S2V)		
ASCORBYL PALMITATE (UNII: QN83US2B0N)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
CETEARETH-15 (UNII: 867H4YOZ8Z)		
MACADAMIA TERNIFOLIA SEED OIL (UNII: 515610SU8C)		
MICA (UNII: V8A1AW0880)		
ISOMALT (UNII: S870P55O2W)		
GREEN TEA LEAF (UNII: W2ZU1RY8B0)		
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)		
OLEA EUROPAEA (OLIVE) LEAF POWDER (UNII: MJ95C3OH47)		
VITIS VINIFERA (GRAPE) SEED OIL (UNII: 930MLC8XGG)		
ASCORBIC ACID (UNII: PQ6CK8PD0R)		
PROPANEDIOL (UNII: 5965N8W85T)		
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)		
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)		
TOCOPHEROL (UNII: R0ZB2556P8)		
ALOE (UNII: V5VD430YW9)		
DECYL OLEATE (UNII: ZGR06DO97T)		
ETHYLHEXYL PALMITATE (UNII: 2865993309)		
WATER (UNII: 059QF0KO0R)		
SHEA BUTTER (UNII: K49155WL9Y)		
ROSMARINUS OFFICINALIS (ROSEMARY) LEAF POWDER (UNII: IJ67X351P9)		
PANTHENOL (UNII: WW9CM0O67Z)		
PHOSPHATIDYLCHOLINE, SOYBEAN (UNII: 1T6N4D9YV6)		
CITRIC ACID (UNII: 2968PHW8QP)		
ORANGE OIL (UNII: AKN3KSD11B)		
NIACINAMIDE (UNII: 25X51I8RD4)		
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)		

CENTELLA ASIATICA (UNII: 7M867G6T1U)				
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-058-14	50 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2025	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M020	04/17/2025	

Labeler - CA Botana International INC (106276728)

Establishment			
Name	Address	ID/FEI	Business Operations
CA Botana International INC		106276728	manufacture(35192-058)

Revised: 5/2025

CA Botana International INC