

**MINERAL SUNSCREEN- zinc oxide spf 50 lotion**  
**ALAINA HEALTHCARE PRIVATE LIMITED**

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**Mineral Sunscreen**  
**Broad Spectrum SPF 50 PA++++**

***Drug Facts***

***Active ingredients***

Zinc Oxide 15%

***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 product is swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

- Shake well.
- Apply liberally 15 minutes before sun exposure.
- Reapply:
  - After 40 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.
- Children under 6 months: ask a doctor.

### ***Inactive Ingredients***

Aqua, Coco-Caprylate/Caprates, Polyglyceryl-3 Polyricinoleate, Isostearic Acid, Dibutyl Adipate, C12-15 Alkyl Benzoate, Glycerin, Polyester-7, Neopentyl Glycol Diheptanoate, Butyloctyl Salicylate, Squalane, VP/Eicosene Copolymer, Polyglyceryl-2 Oleate, Polyhydroxystearic Acid, Polyglyceryl-2 Stearate, Asparagus Racemosus (Asparagus) Root Extract, Picrorhiza Kurroa (Picrorhiza) Root Extract, Cyperus Rotundas (Nut Grass) Root Extract, Sodium Chloride, Phenoxyethanol, Caprylyl Glycol, Sodium EDTA, Tocopherol, Tocotrienols, Ectoin.

### ***Other Information***

Protect this product from excessive heat and direct sun.

### ***Questions?***

Email us at or visit

**Mineral Sunscreen Broad Spectrum SPF 50 PA++++ 5 mL/0.17 fl.OZ**

**Drug Facts**

**Active Ingredients Purpose**  
Zinc Oxide 15%.....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 product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Shake well.
- Apply liberally 15 minutes before sun exposure.
- **Reapply:**
- After 40 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 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: Ask a doctor.

**Inactive Ingredients**

Aqua, Coco-Caprylate/Caprate, Polyglyceryl-3 Polyricinoleate, Isostearic Acid, Dibutyl Adipate, C12-15 Alkyl Benzoate, Glycerin, Polyester-7, Neopentyl Glycol Diheptanoate, Butyloctyl Salicylate, Squalane, VP/Eicosene Copolymer, Polyglyceryl-2 Oleate, Polyhydroxystearic Acid, Polyglyceryl-2 Stearate, Asparagus Racemosus (Asparagus) Root Extract, Pterorhiza Kurroa (Pterorhiza) Root Extract, Cyperus Rotundus (Nut Grass) Root Extract, Sodium Chloride, Phenoxyethanol, Caprylyl Glycol, Sodium EDTA, Tocopherol, Tocotrienols, Ectoin.

**Other Information**

Protect this product from **excessive heat and direct sun.**

**Questions?**

Email us at  
or visit

*Mineral Sunscreen*

Broad Spectrum SPF 50 PA++++  
5 ml / 0.17 fl oz

Apply to clean, dry skin fifteen minutes before sun exposure.

For external use only. Avoid damaged skin and eyes; rinse with water if contact occurs. Stop use if rash develops. Keep away from children. If swallowed, seek medical help immediately.



# Mineral Sunscreen Broad Spectrum SPF 50 PA++++ 50 mL/1.7 fl.OZ



## MINERAL SUNSCREEN

zinc oxide spf 50 lotion

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:73492-152

Route of Administration TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	15 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
AQUA (UNII: 059QF0K00R)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYESTER-7 (UNII: 0841698D2F)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SQUALANE (UNII: GW89575KF9)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
POLYGLYCERYL-2 OLEATE (UNII: 5759J47SAM)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYGLYCERYL-2 STEARATE (UNII: 253MC0P0YV)	
ASPARAGUS RACEMOSUS ROOT (UNII: Y8P1YR4920)	
PICRORHIZA KURROA ROOT (UNII: ZB5K2O2999)	
CYPERUS ROTUNDUS ROOT (UNII: 4B51SRR959)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE SODIUM (UNII: MP1J8420LU)	
TOCOTRIENOLS (UNII: KP2MW85SSQ)	
ECTOIN (UNII: 7GXZ3858RY)	
TOCOPHEROL (UNII: R0ZB2556P8)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73492-152-50	1 in 1 CARTON	03/07/2025	
1		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:73492-152-05	1 in 1 CARTON	03/07/2025	
2		5 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
OTC Monograph Drug	M020	03/04/2025	

**Labeler** - ALAINA HEALTHCARE PRIVATE LIMITED (858720927)

## Establishment

Name	Address	ID/FEI	Business Operations
ALAINA HEALTHCARE PRIVATE LIMITED		858720927	manufacture(73492-152)

Revised: 12/2025

ALAINA HEALTHCARE PRIVATE LIMITED