

**NIA24 SUN DAMAGE DEFENSE BROAD SPECTRUM 100 PERCENT MINERAL
SUNSCREEN SPF 30- titanium dioxide, zinc oxide lotion
NIADYNE 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.

**NIA24 SUN DAMAGE DEFENSE BROAD SPECTRUM SPF 30 100% MINERAL
SUNSCREEN**

Active Ingredients

TITANIUM DIOXIDE 7.064%

ZINC OXIDE 14.00%

Purpose

Sunscreen

Warnings

- For external use only.
- Do not use on damaged or broken skin.
- Stop use and ask a doctor if rash occurs.
- When using this product, keep out of eyes. Rinse well with water to remove.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Non-water resistant product.
- 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 15 or higher and other sun protection measures, including:
 - Limit time in the sun, especially from 10 am – 2 pm.
 - Wear long-sleeve shirts, pants, hats, and sunglasses.
- Children under 6 months of age: Ask a doctor.

Other information

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

Inactive Ingredients

Nicotinate, Octyldodecyl Neopentanoate, Neopentyl Glycol Diheptanoate, Aluminum Starch Octenylsuccinate, Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Stearic Acid, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Cetyl Alcohol, Magnesium Sulfate, Dimethiconol, Polysilicone-11, Caprylyl Glycol, Bisabolol, Tocopheryl Acetate, Aluminum

Hydroxide, Alumina,
Isostearic Acid, Lecithin, Polyhydroxystearic Acid, Polyglyceryl-3 Polyricinoleate, Benzotriazolyl
Dodecyl p-Cresol, Disodium EDTA, Fragrance (Parfum)


• Physician Recommended
• Color and Dye Free
• Non-Comedogenic

| Drug Facts | |
|--|----------------|
| Active Ingredients | Purpose |
| Titanium Dioxide 7.644% | Sunscreen |
| Zinc Oxide 14.007% | Sunscreen |
| Uses | |
| • Helps prevent sunburn | |
| Warnings | |
| • For external use only. | |
| • Do not use on damaged or broken skin. | |
| • Stop use and ask a doctor if rash occurs. | |
| • When using this product, keep out of eyes. Rinse well with water to remove. | |
| • Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| Directions | |
| • Apply liberally 15 minutes before sun exposure. | |
| • Reapply at least every 2 hours. | |
| • Non-water resistant product. | |
| • 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 15 or higher and other sun protection measures, including: <ul style="list-style-type: none"> - Limit time in the sun, especially from 10 am – 2 pm. - Wear long-sleeve shirts, pants, hats, and sunglasses. | |
| • Children under 6 months of age. Ask a doctor. | |
| Inactive Ingredients | |
| Aqua (Water, Eau), Cyclopentasiloxane, Caprylyl/Capric Triglyceride, Myristyl Nicotinate, Octyldodecyl Neopentanoate, Neopentyl Glycol Diheptanoate, Aluminum Stearic Octenylsuccinate, Polyglyceryl-3 Isostearate, Cetyl PEG-10/1 Dimethicone, Hexyl Laurate, Stearic Acid, Polyglyceryl-3 Polydimethylsilyloxyethyl Dimethicone, Cetyl Alcohol, Magnesium Sulfate, Dimethiconol, Polysiloxane-11, Caprylyl Glycol, Bisabolol, Isopropyl Acetate, Aluminum Hydroxide, Alumina, Isostearic Acid, Lecithin, Polyhydroxystearic Acid, Polyglyceryl-3 Polyricinoleate, Benzotriazolyl Dodecyl p-Cresol, Disodium EDTA, Fragrance (Parfum) | |
| Other Information | |
| Protect the product in this container from excessive heat and direct sun. | |

NIA24

Pro-Niacin Powered Skin Care™ For Sun and Age Defense

Rejuvenate, Rehydrate and Protect



**Sun Damage Defense
Broad Spectrum SPF 30
100% Mineral Sunscreen**


| | |
|---------------|-----------------------------|
| SPF 30 Lotion | Pro-Niacin Patented Formula |
|---------------|-----------------------------|

Physician recommended and 100% mineral sunscreen in a lightweight, oil-free lotion that absorbs quickly for sunburn protection.

Formulated with:

- **Pro-Niacin™** to help strengthen the moisture barrier and visibly improve skin tone, texture and look of age spots.
- **Vitamin E** to fight dry skin caused by environmental aggressors.
- **Bisabolol** to moisturize and condition skin.

NADYNE, INC., New York, NY
www.NIA24.com
Made in USA
Covered by US Patents
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e 75 ml / 2.5 fl oz

NIA24 SUN DAMAGE DEFENSE BROAD SPECTRUM 100 PERCENT MINERAL SUNSCREEN SPF 30

titanium dioxide, zinc oxide lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:43115-101 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP) | TITANIUM DIOXIDE | 7.1 g in 100 mL |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 14 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0K00R) | |
| CYCLOMETHICONE 5 (UNII: 0TH5PC10R) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| MYRISTYL NICOTINATE (UNII: 8QWM6I035C) | |

| |
|--|
| OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T) |
| NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X) |
| ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294) |
| POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7) |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X) |
| HEXYL LAURATE (UNII: 4CG9F9W01Q) |
| STEARIC ACID (UNII: 4ELV7Z65AP) |
| POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q) |
| CETYL ALCOHOL (UNII: 936JST6JCN) |
| MAGNESIUM SULFATE ANHYDROUS (UNII: ML30MJ2U7I) |
| DIMETHICONOL (14000 CST) (UNII: M2HW98ZA4V) |
| POLYSILICONE-15 (UNII: F8DRP5BB29) |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) |
| .ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z) |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) |
| ALUMINUM OXIDE (UNII: LM26O6933) |
| ISOSTEARIC ACID (UNII: X33R8U0062) |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) |
| POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W) |
| BENZOTRIAZOLYL DODECYL P-CRESOL (UNII: 298PX4M11X) |
| EDETATE DISODIUM (UNII: 7FLD91C86K) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-------------------|--|----------------------|--------------------|
| 1 | NDC:43115-10 1-75 | 1 in 1 BOX | 12/26/2018 | |
| 1 | | 75 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 not final | part352 | 12/26/2018 | |

Labeler - NIADYNE INC (113220482)

Registrant - NIADYNE INC (113220482)