

NIA 24 SPF 30- homosalate, octisalate, avobenzone, octocrylene 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.

NIA 24 SPF 30

Active Ingredients	Purpose
Homosalate 7.5%.....	Sunscreen
Octisalate 5.0%.....	Sunscreen
Avobenzone 3.0%.....	Sunscreen
Octocrylene 2.6%.....	Sunscreen

Uses - for prevention of sunburn

Warnings For external use only.

When using this product, keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash or irritation develops and lasts.

For children 6 months of age or under , consult a doctor prior to use.

Keep out of reach of children.

If swallowed, get medical help or contact a poison control center right away.

UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.

Directions - Apply a dime sized amount in the morning on cleansed face and neck or over a moisturizer. - Reapply as needed or after towel drying, swimming or perspiring.

Inactive Ingredients

Water (Aqua/Eau), Dipropylene Glycol, Myristyl Nicotinate, Polyester-8, Caprylyl Methicone, Cyclomethicone, Glyceryl Stearate, Polyacrylate-15, Panthenol, Potassium Cetyl Phosphate, Butylene Glycol, Mangifera Indica (Mango) Seed Butter, Methyl Glucose Sesquistearate, Hydrogenated Palm Glycerides, Polyacrylate-17, Dipotassium Glycyrrhizate, Glycine Soja (Soybean) Seed Extract, Ceramide 2, Ceramide 3, Lycium Chinensis Fruit Extract, Vaccinium Angustifolium (Blueberry) Fruit Extract, Arctostaphylos Uva Ursi Leaf Extract, PEG-100 Stearate, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Sorbitan Sesquioleate, Polysorbate 80, Cetyl Alcohol, Tocopheryl Acetate, Xanthan Gum, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Potassium Hydroxide, Disodium EDTA, Phenoxyethanol, Caprylyl Glycol, Myristica Fragrans (Nutmeg) Kernel Extract.

Prevention Now Starts From Within. The benefits of NIA 24™ help to prevent, repair and fight the visible signs of sun damage. Skin Cancer Foundation Facts*: - In our lifetime, 1 in 5 Americans will be victims of skin cancer. - More than 90% of all skin cancers are preventable--- caused by sun exposure. - The risk of melanoma has doubled in the past decade. It is responsible for 75% of all skin cancer-related deaths. *These facts have been provided by the Skin Cancer Foundation. - Improve the appearance of sun damage, hyperpigmentation and brown spots. - Reduce the appearance of fine lines and wrinkle. - Improve skin tone, texture and firmness. - See stronger skin with a better self-defense against visible signs of sun damage and moisture loss. Physician Recommended Allergy Tested Fragrance, Color and Dye Free Non-Comedogenic.

NIA 24 Niacin-Powered Skin Therapy Sun Damage Prevention UVA/UVB Sunscreen Micro Nutrient Deliver: NIACHI SPF 30 PA +++ 5% Pro-Niacin Patented Formula For Moderate to Severe Sun

Damage

Active Ingredients: Homosalate (7.5%), Octisalate (5.0%), Avobenzone (3.0%), Octocrylene (2.6%).
Uses - for prevention of sunburn Warnings For external use only. When using this product, keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash or irritation develops and lasts. For children 6 months of age or under, consult a doctor prior to use. Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away. UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen. e 30mL/1 FLUID OZ. Covered by US Patents 6337065, 6552050, 6464992 NIADYNE, INC., Raieigh, NC 27609/BIORUS sprl, 2 rue Rene Descartes, B-7000 Mons, Belgium 866-NIADYNE (642-3963) www.NIA24.com Made in the USA 12M

PreDamage PostDamage UnDamage NIA24 Niacin Powered Skin Therapy For Moderate Severe Sun Damage PA +++ Sun Damage Prevention UVA(aging)/UVB(burning) Sunscreen MicroNutrient Delivery: NIACIN SPF 30 PA+++ 5% Pro-Niacin Patented Formula A lightweight, non-greasy lotion with SPF 30 and PA+++ that absorbs instantly into skin. Formulated with powerful ingredients that provide UVA (aging rays) and UVB (burning rays) protection from sun damage while helping to repair the skin barrier. - Continuous, deep delivery of Pro-Niacin strengthens the skin barrier. - Pro-Niacin is clinically shown to visibly improve skin tone, texture and hyperpigmentation. - Broad spectrum protection (UVA/UVB) with the highest PA rating, helps defend skin against free radical attack that weakens and ages the skin. - Mango butter provides balanced moisturization without leaving excess. - Ceramides promote healthy, vibrant skin. - Antioxidants protect skin from oxidative stress. RECOMMENDED SKIN CANCER FOUNDATION DAILY USE * These facts have been provided by the Skin Cancer Foundation e 75mL/2.5 FLUID OZ 0141A1 EXP:01/2013 8 51203 00073 7

Covered by US Patents 6337065, 6552050, 6464992 NIADYNE, INC., Raieigh, NC 27609/BIORUS sprl, 2 rue Rene Descartes, B-7000 Mons, Belgium For all consumer inquiries, please call 866-NIADYNE (642-3963) www.NIA24.com Made in the USA 12M NIA24 NIA24 NIA24 NIA24 NIA24 NIA24 NIA24 NIA24 NIA24

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A horizontal banner with a dark, textured background. On the left, the text "NIA 24" is prominently displayed in a large, white, sans-serif font. Below "NIA 24", the words "Niacin-Powered Skin Therapy" are written in a smaller, white font. To the right of this, the text "For Moderate to Severe Sun Damage" is written in a white font, arranged in two lines.



Sun Damage Prevention UVA(aging)/UVB(burning) Sunscreen

MicroNutrient Delivery: NIACIN

SPF 30
PA+++

5% Pro-Niacin®
Patented Formula

A lightweight, non-greasy lotion with SPF 30 and PA+++ that absorbs instantly into skin. Formulated with powerful ingredients that provide UVA (aging rays) and UVB (burning rays) protection from sun damage while helping to repair the skin barrier.

- Continuous, deep delivery of Pro-Niacin® strengthens the skin barrier.
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e 75mL/2.5 FLUID OZ



NIA 24[®]

Niacin-Powered Skin Therapy

For Moderate to Severe Sun Damage

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43115-123
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	26 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
MYRISTYL NICOTINATE (UNII: 8QWM6I035C)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PANTHENOL (UNII: WV9CM0O67Z)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
GLICYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
SOYBEAN (UNII: L7HT8F1ZOD)	
CERAMIDE 2 (UNII: C04977SRJ5)	
CERAMIDE 3 (UNII: 4370DF050B)	
LYCIUM CHINENSE FRUIT (UNII: TG711Q7A1Q)	
LOWBUSH BLUEBERRY (UNII: G90PX41VP0)	
ARCTOSTAPHYLOS UVA-URSILEAF (UNII: 3M5V3D1X36)	
PEG-100 STEARATE (UNII: YD01N1999R)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
ISOHEXADECANE (UNII: 918X10UF1E)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
NUTMEG (UNII: AEE24M3MQ9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43115-123-01	1 in 1 PACKAGE	12/19/2017	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:43115-123-02	1 in 1 PACKAGE	12/19/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/09/2011	

Labeler - Niadyne Inc (113220482)**Establishment**

Name	Address	ID/FEI	Business Operations
Englewood Lab, Inc.		080366903	manufacture(43115-123)

Establishment

Name	Address	ID/FEI	Business Operations
Englewood Lab Korea Co., Ltd.		690104005	manufacture(43115-123)

Revised: 1/2020

Niadyne Inc