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 24TM 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 Fragrace, 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 Severs Sun

Demage

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

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*:

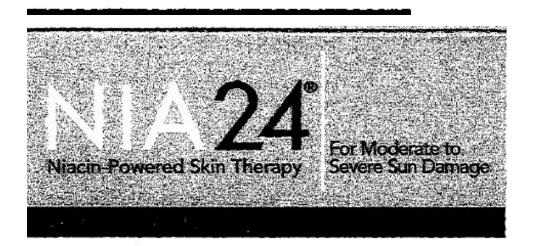
In our lifetime, 1 in 5
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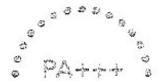
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Sun Damage Prevention UVA(aging)/UVB(burning) Sunscreen

MicroNutrient Delivery: NIACIN

SPF 30 PA+++

5% Pro-Niscin[®] Salenie de Founde

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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75mU2.5 FLUID OZ



For Moderate to Severe Sun Damage

Prevention Now Starts From Within.

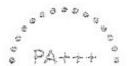
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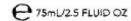
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NIA 24 SPF 30

homosalate, octisalate, avobenzone, octocrylene lotion

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: 4X49 Y0 59 6 W) (OCTIS ALATE - UNII:4X49 Y0 59 6 W)	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	Ctuonath
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
MYRISTYL NICOTINATE (UNII: 8QWM61035C)	
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296 U138 P)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)	
PANTHENOL (UNII: WV9CM0O67Z)	
POTASSIUM CETYL PHO SPHATE (UNII: 03KCY6P7UT)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MANGIFERA INDICA SEED BUTTER (UNII: 40 XD9 M35X2)	
HYDRO GENATED PALM GLYCERIDES (UNII: YCZ8 EM144Q)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0 FE3FX)	
SO YBEAN (UNII: L7HT8F1ZOD)	
CERAMIDE 2 (UNII: C04977SRJ5)	
CERAMIDE 3 (UNII: 4370 DF0 50 B)	
LYCIUM CHINENSE FRUIT (UNII: TG711Q7A1Q)	
LOWBUSH BLUEBERRY (UNII: G90PX41VP0)	
ARCTOSTAPHYLOS UVA-URSI LEAF (UNII: 3M5V3D1X36)	
PEG-100 STEARATE (UNII: YD01N1999R)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
ISO HEXADECANE (UNII: 9 18 X1O UF1E)	
SORBITAN SESQUIOLEATE (UNII: 0 W8 RRI5W5A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
POTASSIUM HYDROXIDE (UNII: WZH3C48 M4T)	
EDETATE DISO DIUM (UNII: 7FLD91C86K)	
PHENO XYETHANO L (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
NUTMEG (UNII: AEE24M3MQ9)	

P	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	

2	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 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