BY NATURE HYDRATING DAY SPF 15- avobenzone, oxybenzone, octyl methoxycinnamate cream

Lanocorp Pacific Ltd

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.

Drug Facts

ACTIVE INGREDIENTS

Avobenzone 3% Oxybenzone 3% Octylmethoxycinnamate 7.5%

USES

Helps prevent sunburn

WARNINGS

For external use only. Do not use on broken or damaged skin.

Skin Cancer/Skin Ageing Alert: Spending time in the sun increases your risk of skin cancer and early skin ageing. This product has been shown only to help prevent sunburn, not skin cancer or early skin ageing.

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

Stop use and ask a doctor if any rush occurs.

Keep out of reach of children.

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DIRECTIONS

Apply liberally and evenly 15 minutes before sun exposure Children under 6 months of age: Ask a doctor Apply to all skin exposed to the sun Reapply at least every 2 hours Use a water resistant sunscreen if swimming or sweating

ACTIVE INGREDIENTS

Avobenzone 3% Oxybenzone 3% Octyl methoxycinnamate 7.5%

Sunscreen

INACTIVE INGREDIENTS

Water

Ethylhexyl palmitate

Caprylic triglyceride

Capric triglyceride

Polyacrylamide

c13-14 Isoparaffin

Laureth-7

Polysorbate 60

Cetearyl alcohol

Glycerin

Cyclopentasiloxane

Clyclotetrasiloxane
dimethiconol
Caprylhydroxamic acid
phenoxyethanol
methylpropanediol
tocopheryl acetate (vitamin e)
lanolin (medical grade)
Sorbitan stearate
Hydrolyzed (Marine) collagen
Tetrasodium EDTA
Actinidia chinensis (kiwi) fruit extract
Leptospermum scoparium Mel UMF 15+ Active Manuka Honey





Hydrating Day Crème

SPF15

Infused with

Moisturizing Collagen & Vitamin E

Net Wt. 60g / 2oz

Made in New Zealand

Created from New Zealand's natural environment using the finest native resources, this smooth and hydrating day crème will leave your skin soft, hydarated and nourished.

Directions:

Gently massage this exquisite crème into your skin in the morning following cleansing to leave you feeling nourished, hydrated and ready to face the day.

Store below 30° Celsius



125 Waterloo Road, Christchurch, New Zealand
10 Chester Drive, North Harrow,
Middlesex HA2 7PU, United Kingdom

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BY NATURE HYDRATING DAY SPF 15

avobenzone, oxybenzone, octyl methoxycinnamate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43617-3416
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.5 g in 50 g	
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1.5 g in 50 g	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 50 g	

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Ethylhexyl palmitate (UNII: 2865993309)	
Tricaprylin (UNII: 6P92858988)	
Tricaprin (UNII: O1PB8EU98M)	
SODIUM ACRYLO YLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPA.S) (UNII: 5F4963KLHS)	
C13-14 Isoparaffin (UNII: E4F12ROE70)	
Laureth-7 (UNII: Z95S6G8201)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Glycerin (UNII: PDC6A3C0OX)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Cyclomethicone 4 (UNII: CZ227117JE)	
Dimethiconol (41 MPA.S) (UNII: 343C7U75XW)	
Caprylhydroxamic acid (UNII: UPY805K99W)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Methylpropanediol (UNII: N8F53B3R4R)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8 X80 D2L0)	
Lanolin (UNII: 7EV65EAW6H)	
Sorbitan monostearate (UNII: NVZ4I0H58X)	
HYDROLYSED MARINE COLLAGEN (ENZYMATIC; 2000 MW) (UNII: 2WID9OCG7P)	
EDETATE SO DIUM (UNII: MP1J8 420 LU)	
KIWI FRUIT (UNII: 71ES77LGJC)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:43617-3416-2	1 in 1 BOX		
1	60 g in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	08/01/2012		

Labeler - Lanocorp Pacific Ltd (594482114)

Establishment			
Name	Address	ID/FEI	Business Operations
Lanocorp Pacific Ltd		594482114	manufacture(43617-3416)

Revised: 8/2014 Lanocorp Pacific Ltd