

LANOCREME HYDRATING DAY SPF15- 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%

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

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.

Keep out of reach of children.

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

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

Stop use and ask a doctor if any rash occurs.

INACTIVE INGREDIENTS

Water

Ethylhexyl palmitate

Caprylic triglyceride

Capric triglyceride

Polyacrylamide

c13-14 Isoparaffin

Laureth-7

Polysorbate 60

Cetearyl alcohol

Glycerin

Cyclopentasiloxane

Clycotetrasiloxane

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



Lanocrème®

**HYDRATING
DAY CREAM**

**SPF
15**

Advanced Collagen Enriched Formulation

Enriched with Active Manuka Honey

Net Wt. 50g / 1¾oz

FRONT

Directions:
Gently massage into your face and neck after cleansing.

Manufactured by:

Lanocrème 

Hypoallergenic

Made in New Zealand

www.lanocrema.com

BACK

LANOCREME HYDRATING DAY SPF15

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Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:43617-3415 |
| 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: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 1.5 g in 50 g |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 7.5 g in 50 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| Water (UNII: 059QF0KO0R) | |
| Ethylhexyl palmitate (UNII: 2865993309) | |
| Tricaprylin (UNII: 6P92858988) | |
| Tricaprin (UNII: O1PB8EU98M) | |
| SODIUM ACRYLOYLDIMETHYLTAURATE-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: 9E8X80D2L0) |
| Lanolin (UNII: 7EV65EAW6H) |
| Sorbitan monostearate (UNII: NVZ4I0H58X) |
| HYDROLYSED MARINE COLLAGEN (ENZYMATIC; 2000 MW) (UNII: 2WID9OCG7P) |
| EDETATE SODIUM (UNII: MP1J8420LU) |
| KIWI FRUIT (UNII: 71ES77LGJC) |
| HONEY (UNII: Y9HIV576FH) |

| Packaging | | | | |
|------------------|------------------|---------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:43617-3415-1 | 1 in 1 BOX | | |
| 1 | | 50 g in 1 JAR | | |

| Marketing Information | | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part352 | 04/30/2012 | |

Labeler - Lanocorp Pacific Ltd (594482114)

| Establishment | | | |
|----------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| Lanocorp Pacific Ltd | | 594482114 | manufacture |