

**LAPCOS DOUBLET COVER CUSHION 01 ROSY IVORY- titanium dioxide, octinoxate, octisalate powder
LAP CO.,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.

ACTIVE INGREDIENT

Active ingredients: Titanium Dioxide 13.7%, Ethylhexyl Methoxycinnamate 6.7%, Ethylhexyl Salicylate 4.0%

INACTIVE INGREDIENT

Inactive ingredients: Water, Cyclopentasiloxane, Butylene Glycol, PEG-8 Dimethicone, Glycerin, Niacinamide, Butylene Glycol Dicaprylate/Dicaprate, Caprylyl Methicone, Trimethylsiloxysilicate, Pentylene Glycol, Iron Oxides (CI 77492), Rosa Canina Fruit Oil, Tremella Fuciformis (Mushroom) Extract, Hydrolyzed Pearl, Honey Extract, Actinidia Polygama Fruit Extract, Dimethicone, Magnesium Sulfate, Synthetic Fluorophlogopite, Diphenyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Acrylates/Stearyl Acrylate/Dimethicone Methacrylate Copolymer, Stearic Acid, Alumina, Dimethicone Crosspolymer, Aluminum Hydroxide, Triethoxycaprylylsilane, Disteardimonium Hectorite, Dimethicone/Vinyl Dimethicone Crosspolymer, Ethylhexylglycerin, Adenosine, Hydrogenated Castor Oil Isostearate, Caprylic/Capric Triglyceride, Hydrogenated Lecithin, Polyglutamic Acid, Ethyl Hexanediol, Ceramide 3, Polysorbate 20, Palmitoyl Oligopeptide, Palmitoyl Tetrapeptide-7, Carbomer, Disodium EDTA, Phenoxyethanol, Fragrance(Parfum), Iron Oxides (CI 77491), Iron Oxides (CI 77499)

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings: For external use only Avoid contact with eyes. Discontinue use if signs of irritation or rashes appear. Replace the cap after use. Keep Out of Reach of Children

DESCRIPTION

Uses: Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Directions: Apply liberally 15 minutes before sun exposure. Reapply at least every 2 hours. 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 value of 15 or higher and other sun protection measures including: Limit time in the sun, especially from 10 a.m. - 2 p.m. Wear long-sleeved shirts, pants, hats, and sunglasses. Children under 6 months of age: Ask a doctor.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



LAPCOS DOUBLET COVER CUSHION 01 ROSY IVORY

titanium dioxide, octinoxate, octisalate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71379-030
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 Dio xide	1.64 g in 12 g
Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	0.80 g in 12 g
Octisalate (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	Octisalate	0.48 g in 12 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Butylene Glycol (UNII: 3XUS85K0RA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71379-030-02	1 in 1 CARTON	04/01/2017	
1	NDC:71379-030-01	12 g in 1 CONTAINER; 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	04/01/2017	

Labeler - LAP CO.,LTD (689041115)**Registrant** - LAP CO.,LTD (689041115)**Establishment**

Name	Address	ID/FEI	Business Operations
LAP CO.,LTD		689041115	relabel(71379-030)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc		689049693	manufacture(71379-030)

Revised: 5/2017

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