

LOVEA - titanium dioxide cream
Laboratoires Biocos

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.

Natural mineral Sunscreen SPF 30

Drug Facts

| Active ingredients | Purpose |
|--------------------------------|-----------|
| Titanium dioxide (12,1%) | Sunscreen |

Use

• Helps prevent sunburn • Higher SPF gives more sunburn protection • Provides high protection against 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. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• Apply generously and evenly to all areas 15 minutes before sun exposure • Spray on hands to apply to face • Reapply at frequent intervals and after swimming, sweating or towel drying • Ask a doctor before use on children under six months of age

Other information

Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

Inactive ingredients

DICAPRYLYL CARBONATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, COCO-CAPRYLATE, COCO-CAPRYLATE/CAPRATE, ALCOHOL*, ARGANIA SPINOSA KERNEL OIL*, ALUMINIUM HYDROXIDE, STEARIC ACID, POLYGLYCERYL-3 DIISOSTEARATE, PARFUM (FRAGRANCE), COCOS NUCIFERA (COCONUT) OIL, GARDENIA TAHITENSIS FLOWER, OLEYL ALCOHOL, ZANTHOXYLUM ALATUM FRUIT EXTRACT. *Ingredients from organic farming



LOVEA

titanium dioxide cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76363-029 |
| 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 dioxide | 12.1 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| Dicaprylyl carbonate (UNII: 609A3V1SUA) | |
| Polyglyceryl-3 Diisostearate (UNII: 46P231IQV8) | |
| Stearic Acid (UNII: 4ELV7Z65AP) | |
| Aluminum hydroxide (UNII: 5QB0T2IUN0) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| Coco-caprylate (UNII: 4828G836N6) | |
| Coco-caprylate/caprate (UNII: 8D9H4QU99H) | |
| Alcohol (UNII: 3K9958V90M) | |
| ARGAN OIL (UNII: 4V59G5UW9X) | |
| CAPRYLYL/CAPRYL OLIGOGLUCOSIDE (UNII: E00JL9G9K0) | |
| COCONUT OIL (UNII: Q9L0O73W7L) | |

| | |
|--|--|
| GARDENIA TAITENSIS FLOWER (UNII: T0OCU8201Y) | |
| ZANTHOXYLUM ARMATUM VAR. ARMATUM FRUIT (UNII: ER3FV125H7) | |
| oleyl alcohol (UNII: 172F2WN8DV) | |
| LINALOOL, (+/-)- (UNII: D81QY6I88E) | |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) | |
| P-METHYL ANISOLE (UNII: 10FAI0OR9W) | |
| BENZYL BENZOATE (UNII: N863NB338G) | |
| METHYL BENZOATE (UNII: 6618K1VJ9T) | |
| BENZYL SALICYLATE (UNII: WAO5MKN9TU) | |
| FARNESOL (UNII: EB41QIU6JL) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--------------------------|----------------------|--------------------|
| 1 | NDC:76363-029-11 | 128 g in 1 BOTTLE, SPRAY | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 04/26/2012 | |

Labeler - Laboratoires Biocos (774179378)

Registrant - Laboratoires Biocos (774179378)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|---------------------|
| Laboratoires Biocos | | 774179378 | manufacture |

Revised: 4/2012

Laboratoires Biocos