

3CE FULL COVER CONCEALER 001- titanium dioxide liquid

Nanda 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 Ingredient: Titanium Dioxide 13.0%

INACTIVE INGREDIENT

Inactive Ingredients: Water, Cyclopentasiloxane, Methyl Methacrylate Crosspolymer, Butylene Glycol, Cetylhexanoate, Triethylhexanoin, Mica (CI 77019), Cetyl PEG/PPG-10/1 Dimethicone, Trimethylsiloxysilicate, Iron Oxides (CI 77492), Disteardimonium Hectorite, Dicaprylyl Carbonate, Beeswax, Polyglyceryl-4 Isostearate, Magnesium Sulfate, Sorbitan Isostearate, Dimethicone/Vinyl Dimethicone Crosspolymer, Iron Oxides (CI 77491), Triethoxycaprylylsilane, Aluminum Hydroxide, Methylparaben, Chlorphenesin, Iron Oxides (CI 77499), Silica, Propylparaben, Disodium EDTA, Aloe Barbadensis Leaf Juice, Polyvinylalcohol Crosspolymer, Sodium Hyaluronate, Glycyrrhiza Glabra (Licorice) Root Extract, Natto Gum, Nylon-12 Fluorescent Brightener 230 Salt, Potassium Sorbate, Sodium Benzoate

PURPOSE

Purpose: Sunscreen

CAUTION

CAUTION: 1. Discontinue use and consult a doctor when - your skin irritates, swells, itches, shows spots on areas applied - your skin reacts similarly with above when exposed to sunlight 2. Avoid applying on wounded, irritated, troubled areas 3. After the use - keep the cap closed - keep it out of children's reach - keep it away from exposure to sunlight, high and low temperatures

DESCRIPTION

INSTRUCTIONS: A stick type concealer with sleek ends can be used on a variety of areas from narrow to wide areas on face.

Directions: Apply on concerned area with rednesses, dark spot areas to brighten up.

PACKAGE LABEL PRINCIPAL DISPLAY PANEL



3CE FULL COVER CONCEALER 001

titanium dioxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60764-098
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	0.65 g in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0 KO0R)	
Butylene Glycol (UNII: 3XUS85K0 RA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60764-098-02	1 in 1 CARTON	08/20/2016	
1	NDC:60764-098-01	5 mL in 1 BOTTLE; 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	08/20/2016	

Labeler - Nanda Co., Ltd (557816075)

Registrant - Nanda Co., Ltd (557816075)

Establishment

Name	Address	ID/FEI	Business Operations
Nanda Co., Ltd		557816075	repack(60764-098)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc.		689049693	manufacture(60764-098)

Revised: 10/2016

Nanda Co., Ltd