

BB CREAM- titanium dioxide cream
Janssen Cosmetics GmbH

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.

BB Cream

Drug Facts

Active Ingredients: Titanium Dioxide 11.4% Purpose: Sunscreen

Ingredients

Ingredients: small-capsWater, Aloe Barbadensis Leaf Juice, Caprylic/Capric Triglyceride, Glycerin Octyldodecyl Stearoyl Stearate, Diisopropyl Sebacate, Cetearyl Alcohol, Glyceryl Stearate, Silica, Polyhydroxystearic Acid, Potassium Palmitoyl Hydrolyzed Wheat Protein, CI 77 492 [Iron Oxides], Butyrospermum Parkii Butter, Benzyl Alcohol, Microcrystalline Cellulose, Cetyl Alcohol, Alumina, Stearic Acid, Tocopherol, Citric Acid, Hydrolyzed Beta Maritima Extract, CI 77 491 [Iron Oxides], Solanum Lycopersicum Seed Oil, [Solanum Lycopersicum (Tomato) Seed Oil], Xanthan Gum Lavandula Angustifolia Oil, Helianthus Annuus Seed Oil, [Helianthus Annuus (Sunflower) Seed Oil], Cellulose Gum, CI 77 499 [Iron Oxides], Dehydroacetic Acid, Vaccinium Macrocarpon Seed Oil [Vaccinium Macrocarpon (Cranberry) Seed Oil], Cellulose, Sorbic Acid, Sodium Hydroxide

Warning

For External use only. Not to be swallowed. Avoid contact with the eyes. If contact occurs rinse eyes. Discontinue use if signs of irritation or rash appear. If irritation or rash persists, consult a doctor

Directions

Directions: Simply distribute over the skin for a natural finish

Principal Display Panel

BB Cream



BB CREAM

titanium dioxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:24653-282

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3.42 g in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SHEA BUTTER (UNII: K49155WL9Y)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALUMINUM OXIDE (UNII: LM26O6933)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SOLANUM LYCOPERSICUM (UNII: 0243Q4990L)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
SORBIC ACID (UNII: X045WJ989B)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24653-282-02	1 in 1 CARTON		
1	NDC:24653-282-01	30 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2013	

Labeler - Janssen Cosmetics GmbH (499187946)

Registrant - Janssen Cosmetics GmbH (499187946)

Establishment

Name	Address	ID/FEI	Business Operations
Janssen Cosmetics GmbH		499187946	manufacture(24653-282)

Establishment

Name	Address	ID/FEI	Business Operations
Dr. Sacher		341926681	api manufacture(24653-282)

Revised: 1/2013

Janssen Cosmetics GmbH