

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-capssmall-capsWater, Aloe Barbadensis Leaf Juice, Caprylic/Capric Triglyceride, Glycerin Octyldodecyl Stearoyl Stearate, Diisopropyl Sebacate, Cetearyl Alcohol, Glyceryl Sterate, 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

AB 1212915
Art. 021847

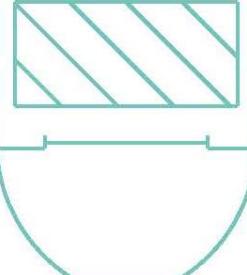
Tonet dagspleje | Farget dag krem i Tonad, världande dagcreme | Sävytävä päivävoide | Krém do dne s cor | Renklendilmiş günük bakım kremlı | Toniran dnevni kreml | Tónovaný denní krém | Toniegt røaekrem | Szinezett napali apró krém | Tonets dienas kréms | Sutekantic atspalvi dieninis kremas | Koloryzujący krem na dzień | Cremă cu pigment | Obarvana dnevna krema | Tónovaný denívý krém |
كريم للختالة الشاملة البشرة مع رائحة الشمس

Active Ingredients: titanium dioxide 11.4%
Cosmetic Ingredients: Water, aloe barbadensis leaf juice, caprylic/capric triglyceride, glycerin, octylidodecyl stearoyl stearate, diisopropyl sebacate, cetearyl alcohol, glyceril stearate, silica, polyhydroxystearic acid, potassium palmitate, hydrolyzed wheat protein, butyrospermum parkii butter [butyrospermum parkii (shea) butter], benzyl alcohol, microcrystalline cellulose, octyl alcohol, alumin, stearyl acid, tocopherol, citric acid, geranial, betamimetic extract, solanum lycopersicum (tomato) seed oil, xanthan gum, lavandula angustifolia oil, helianthus annuus seed oil [helianthus annuus (sunflower) seed oil], cellulose gum, dehydroacetic acid, vaccinium macrocarpon oil [vaccinium macrocarpon (cranberry) seed oil], cellulose, sorbic acid, sodium hydroxide, limonene, geraniol, G 77 492 [iron oxides], CI 77 491 [iron oxides], CI 77 499 [iron oxides]



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JANSSEN
COSMETICS

ALL SKIN NEEDS
OPTIONS TOUTE PEAU

BB Cream
All-in-One Perfection
SPF 25

NET WT 1.0 OZ. 30 ml

Rez. 4C48

Crema giorno, SPF 25, tutto in uno per levigare la pelle e renderla perfetta. Protegge, leniva, idrata e corregge. A base di filtri UV minerali, Aloe Vera e Vitamina E. Distribuire semplicemente sulla pelle per un effetto naturale.

Tägliche All-in-One Pflegecreme für ebenmäßige und perfekte Haut, SPF 25. Schützt, pflegt, glättet und korrigiert. Mit mineralischem UV-Filter, Aloe Vera und Vitamin E. Für ein natürliches Finish einfach über die Haut verteilen.

BB Крем-перфектор 4 в 1 / SPF 25. Моментально выравнивает цвет лица, осветляет, снимает покраснение, защищает от свободных радикалов и солнечных лучей С минеральным УФ-фильтром, алоэ вера и витамином Е. Наносите на предварительно очищенную кожу.

All-in-one verzorgingscrème voor daagelijks gebruik voor een gladde, perfecte huid met SPF 25. Beschermt, verzorgt en maskert. Zorgt voor een gladde huid. Bevat op minerale gebaseerd UV-filter, aloë vera en vitamine E. Eenvoudig op de huid aanbrengen voor een natuurlijke uitstraling.

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 DIO XIDE (UNII: 15FIX9V2JP) (TITANIUM DIO XIDE - UNII:15FIX9V2JP)	TITANIUM DIO XIDE	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)	
CETO STEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
SILICON DIO XIDE (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)	
FERROSOFERRIC 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