

MELAFADIN DAY PROTECTION- titanium dioxide, octinoxate, octocrylene 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.

Melafadin Day Protection

Active Ingredients

Titanium Dioxide: .99%, Octinoxate: 7.49% and Octocrylene: 6.0% Purpose: Sunscreen

Ingredients:

AQUA [WATER], PROPYLHEPTYL CAPRYLATE, ALCOHOL DENAT., BUTYLENE GLYCOL, NYLON-12, CAPRYLIC/CAPRIC TRIGLYCERIDE, GLYCERIN, CETEARYL ALCOHOL, ARACHIDYL ALCOHOL, SACCHARIDE ISOMERATE, TRICONTANYL PVP, METHYLENE, BIS-BENZOTRIAZOLYL TETRAMETHYLBUTYLPHENOL, BIS-ETHYLHEXYLOXYPHENOL, METHOXYPHENYL TRIAZINE, ETHYLHEXYL TRIAZONE, SIGESBECKIA ORIENTALIS EXTRACT, RABDOSIA RUBESCENS EXTRACT, ALUMINUM HYDROXIDE, BEHENYL ALCOHOL, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, GLUCOSE, CHONDRUS CRISPUS (CARRAGEENAN) EXTRACT, UNDECYLENOYL PHENYLALANINE, UNDECYLENIC ACID, DIACETYL BOLDINE, POLYISOBUTENE, SODIUM ACRYLATE/, SODIUM ACRYLOYLDIMETHYLAURATE COPOLYMER, XANTHAN GUM, CAPRYLYL/CAPRYL GLUCOSIDE, CETEARYL GLUCOSIDE, ARACHIDYL GLUCOSIDE, DECYL GLUCOSIDE, HYDROGEN DIMETHICONE, TOCOPHEROL, BHT, TETRASODIUM IMINODISUCCINATE, CAPRYLYL GLYCOL, ETHYLHEXYLGLYCERIN, PROPYLENE GLYCOL, TROMETHAMINE, CITRIC ACID, PARFUM [FRAGRANCE], BUTYLPHENYL METHYLPROPIONAL, HEXYL CINNAMAL, ALPHA-ISOMETHYL IONONE, LINALOOL, GERANIOL, CITRONELLOL, PHENOXYETHANOL, METHYLPARABEN

Warnings

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

Keep out of reach of children.

Directions

Distribute over the facial skin each morning

Outside Box Packaging

Image of 310 box



MELAFADIN DAY PROTECTION			
titanium dioxide, octinoxate, octocrylene cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24653-310
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	.30 g in 50 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.80 g in 50 mL	
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	2.25 g in 50 mL	
Inactive Ingredients			
Ingredient Name	Strength		

WATER (UNII: 059QF0KO0R)
PROPYLHEPTYL CAPRYLATE (UNII: 991Z19V2OD)
ETHANOLAMINE OLEATE (UNII: U4RY8MRX7C)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
NYLON-12 (UNII: 446U8J075B)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
GLYCERIN (UNII: PDC6A3C0OX)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)
SACCHARIDE ISOMERATE (UNII: W8K377W98I)
TRICONTANYL POVIDONE (4 TRICONTANYL BRANCHES/REPEAT) (UNII: N0SS3Q238D)
BISOTRIZOLE (UNII: 8NT850T0YS)
BEMOTRIZINOL (UNII: PWZ1720CBH)
ETHYLHEXYL TRIAZONE (UNII: XQN8R9SAK4)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
DOCOSANOL (UNII: 9G1OE216XY)
SUNFLOWER OIL (UNII: 3W1JG795YI)
DEXTROSE (UNII: IY9XDZ35W2)
CHONDRUS CRISPUS (UNII: OQS23HUA1X)
UNDECYLENIC ACID (UNII: K3D86KJ24N)
DIACETYL BOLDINE (UNII: 37727Z7M0I)
POLYISOBUTYLENE (200000 MW) (UNII: Z6Y0210591)
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)
XANTHAN GUM (UNII: TTV12P4NEE)
CAPRYLYL/CAPRYL OLIGOGLUCOSIDE (UNII: E00JL9G9K0)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
TETRASODIUM IMINO DISUCCINATE (UNII: GYS41J2635)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
TROMETHAMINE (UNII: 023C2WHX2V)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
GERANIOL (UNII: L837108USY)
.BETA.-CITRONELLOL, (R)- (UNII: P010UT964K)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
METHYLPARABEN (UNII: A2I8C7HI9T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24653-310-02	1 in 1 BOX		
1	NDC:24653-310-01	50 mL in 1 JAR		

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(24653-310)

Revised: 1/2013

Janssen Cosmetics GmbH