

FACE GUARD 30 SPF- octinoxate and 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.

Face Guard SPF 30

Ethylhexyl Methoxycinnamate - 7%

TITANIUM DIOXIDE - 1%

Inactive Ingredients

Aqua [water], C12-15 alkyl benzoate, butylenes glycol, dicaprylyl carbonate, DI-C12-13 alkyl malate, methyl glucose sesquistearate, BIS-ethylhexyloxyphenol methoxyphenyl triazine, steareth-21, diethylamino hydroxybenzoyl hexyl benzoate, cetearyl alcohol, methylene,BIS-benzotriazolyl tetramethylbutylphenol, glyceryl stearate,ethylhexyl triazone, ectoin, aluminum hydroxide, dimethicone, glyceryl caprylate, trimethylsiloxysilicate, xanthan gum, decyl glucoside, lecithin, hydrogen dimethicone, BHT, ascorbyl palmitate, tocopherol, tetrasodium glutamate diacetate, propylene glycol, citric acid, sodium hydroxide, phenoxyethanol, methylparaben

Ask a Doctor

Discontinue use if signs of irritation or rash appear. If irritation or rash persists consult a doctor

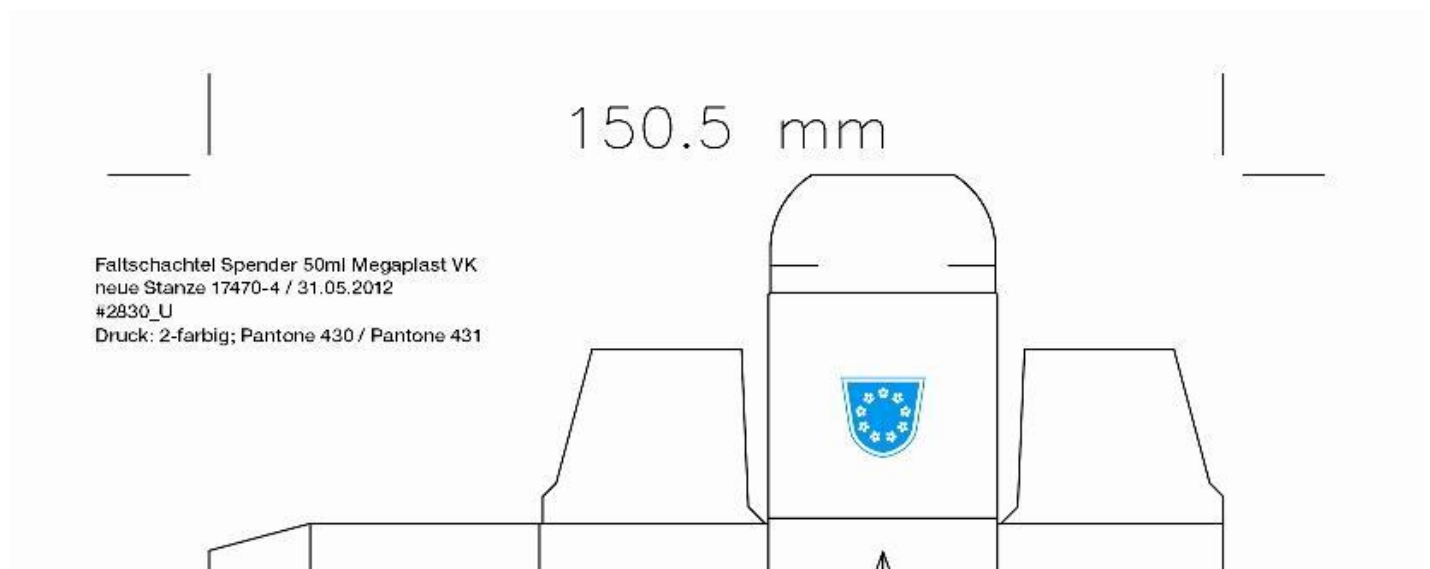
Directions

Simply apply onto the face, neck and neckline after cleansing in the morning and then apply the usual day cream on top

Children under six months of age: consult a doctor

Keep out of reach of children

Front Panel of Box



252.6 mm



Active ingredients: ethylhexyl methoxycinnamate, titanium dioxide (nano) 5.0%

Ingredients: Aqua (water), C12-15 alkyl benzoate, butylene glycol, dioctyl dimethyl carbonate, Di-C12-13 alkyl maleate, methylglycose heptascorbate, BIS-ethylhexyloxyphenol methoxyphenyl triazine, steareth-21, 2-ethylamino hydroxybenzoyl hexyl benzoate, cetylalcol, cetylalcol, triethylene B3-benzoyl acetyl tetraethylbutylphenol, glyceryl stearate, ethylhexyl triazone, acolin, aluminum hydroxide, dimethicone, glyceryl acrylate, dimethylsiloxyl crosspolymer, xanthan gum, cetyl glucoside, sorbitol, hydrogen diethylenetriamine, BHT, ascorbyl palmitate, tocopherol, tetraoctylsiloxane, dimethicone copolymer, glycol, citric acid, sodium hydroxide, polyethylhexyl methoxycinnamate

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.



UV protection concentrate, SPF 30, with photostable UVA and UVB filters.

Idea for all skin types and for combining with all skin care products. With cell protection factor (actin).

Directions: Simply apply onto the face, neck and neckline after cleansing in the morning and then apply the usual day cream on top. Children under six months of age: consult a doctor.

Lichtschutzkonzentrat, SPF 30 mit photostabilen UVA- und UVB-Filtern. Für jeden Hauttyp und mit jeder Tagespflege kombinierbar. Mit Zell-schutzfaktor Estoin. Auftragen und gewöhnlich Tagescreme darüber geben.

Concentré protection UV, SPF 30 avec protection UVA et UVB photo-stable. Idéal pour toutes types de peau et à combiner avec tous les crèmes de jour. Contient un facteur de protection cellulaire à l'Estoin. À appliquer sous votre crème de jour habituelle.

Protezione UV SPF30 (concentrato) con filtri fotostabili UVA e UVB. Ideale protezione eguagliata per tutti i tipi di pelle. Con Estoin il prodotto protegge la pelle. Applicare sul viso e quindi stendere la crema di giorno sopra.

ALL SKIN NEEDS
OPTION 5 TOUTE PEAU

Face Guard
SPF 30
Skin
Protecteur

NET. 1.6 FL. OZ. 50 ml e

Concentrado con protección UV, FPS 30 con filtros UVA y UVB fotostables. Ideal para todo tipo de pieles y para combinar con cada crema de día. Con factor de protección celular (actoin).

Directions: Apply y aplicar a crema de día correspondiente.

Легкая солнцезащитная основа под дневной крем (SPF 30) со стабилизированными UVA- и UVB-фильтрами. Подходит для всех типов кожи, сочетается со всеми средствами дневного ухода. Содержит защитный компонент Estoin. Наносить под дневной крем.

Emulsie met UV bescherming, SPF 30 met UV-bestendige UVA- en UV-B-filters. Ideaal voor alle huidtypen en met alle dag-cremes te combineren. Bevat actoin voor actieve bescherming. Onder de gebruikelijke dagcrème aanbrengen.

紫外线防护精华。SPF30不感光型UVB、UVS防晒保护功能。适合所有类型的皮肤。与日间护肤产品搭配使用。在面霜之前使用。特含艾克多因。



Ref. 19287-01

17470-4

Druckseite

FACE GUARD 30 SPF

octinoxate and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24653-830
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.5 g in 50 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	.5 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
DI-C12-15 ALKYL FUMARATE (UNII: A1CB3Z898P)	
GLUCAMETACIN (UNII: N1EXE5EHAN)	
BEMOTRIZINOL (UNII: PWZ1720CBH)	
STEARETH-21 (UNII: 53J3F32P58)	
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
BISOTRIZOLE (UNII: 8NT850T0YS)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ETHYLHEXYL TRIAZONE (UNII: XQN8R9SAK4)	
ECTOINE (UNII: 7GXZ3858RY)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
XANTHAN GUM (UNII: TTV12P4NEE)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24653-830-02	1 in 1 BOX		
1	NDC:24653-830-01	50 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	06/01/2012	

Labeler - Janssen Cosmetics GmbH (499187946)

Registrant - Janssen Cosmetics GmbH (499187946)

Establishment

Name	Address	ID/FEI	Business Operations
Janssen Cosmetics GmbH		499187946	manufacture(24653-830)

Revised: 10/2012

Janssen Cosmetics GmbH