

OPTIMAL TINTED COMPLEXION- ethylhexyl methoxycinnamate 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.

Optimal Tinted Complexion Cream

Drug Facts

Active Ingredients: ethylhexyl methoxycinnamate 7.0% Purpose: Sunscreen

Inactive Ingredients

Inactive Ingredients: Aqua [water], caprylic/capric triglyceride, butylene glycol, dicaprylyl carbonate, C12-15 alkyl benzoate, cetearyl

alcohol, methyl glucose sesquistearate, CI 77891 [titanium dioxide], glyceryl stearate, nylon-12, saccharide isomerate, ascorbyl

palmitate, BHT, tocopherol, lauroyl lysine, lecithin, disodium EDTA, citric acid, parfum [fragrance], hexyl cinnamal, hydroxyisohexyl 3-cyclohexene carboxaldehyde, butylphenyl methylpropional, alpha-isomethylionone, benzyl salicylate, citronellol, linalool, limonene, benzyl benzoate, phenoxyethanol, methylparaben, propylparaben, butylparaben, ethylparaben, isobutylparaben, CI 77 492 [iron oxides], CI 77 491 [iron oxides], CI 77 499 [iron oxides]

Warning Section

Avoid contact with eyes. Keep out of reach of children. For External use only. Does not replace the use of sun products in care of sun exposure

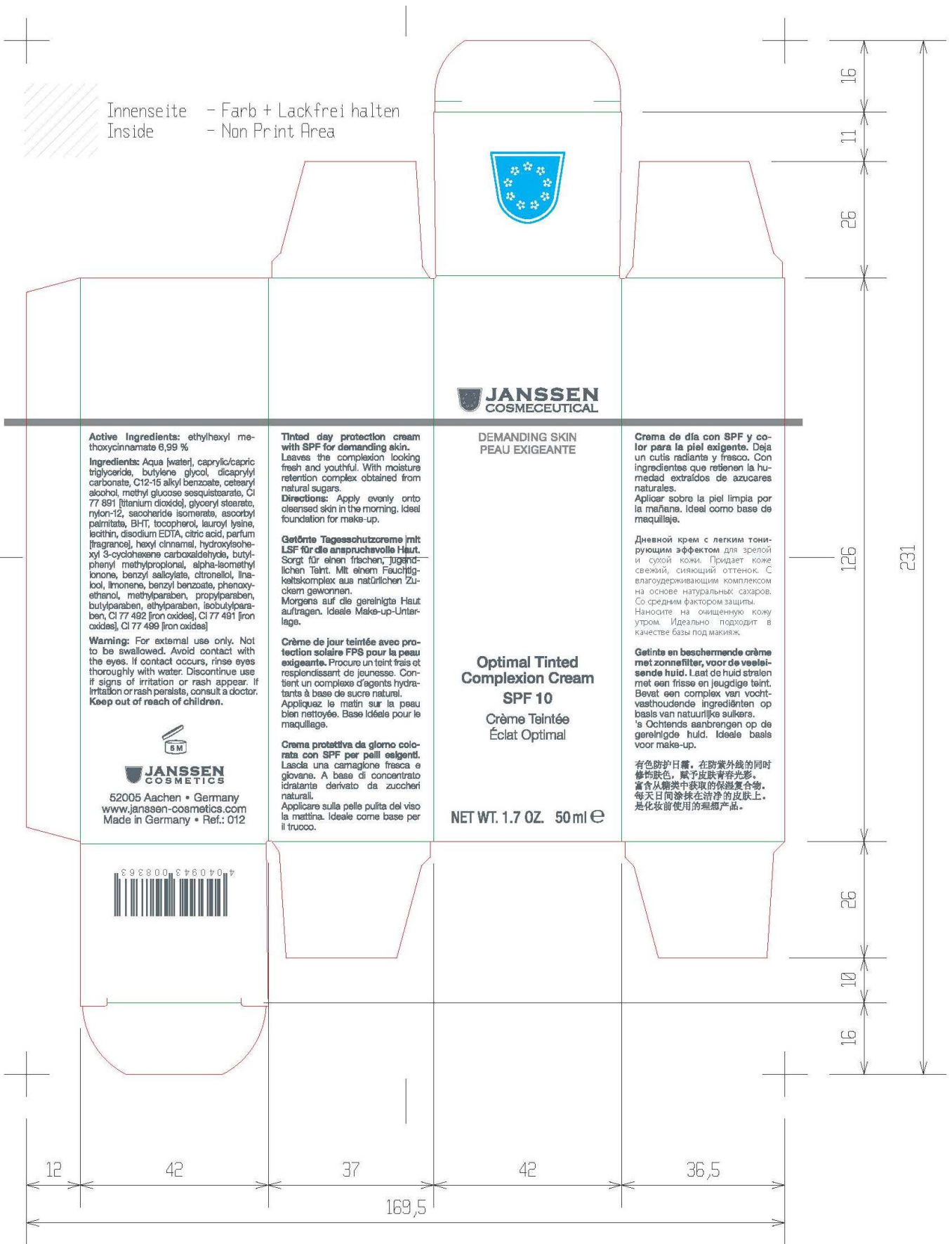
Ask Doctor Section

Discontinue use and consult a doctor if signs of rash or irritation develops and persists

Direction:

Apply evenly onto cleansed skin in the morning. Ideal foundation for make-up

Principal Display



Principal Display Product Tube



DEMANDING SKIN
PEAU EXIGEANTE

**Optimal Tinted
Complexion Cream
SPF 10**
Crème Teintée

NET WT. 1.7 OZ. 50 ml e

Getönte Tagescreme mit LSF.
Auf die gereinigte Haut auftragen.
Tinted day cream with SPF.
Apply onto cleansed skin.
**Crème de jour teintée avec
protection solaire FPS.**
Appliquez sur la peau bien nettoyée.
**Crema colorata da giorno
con SPF.**
Applicare dopo la detersione sulla
pelle del viso.
Crema de día con color y SPF.
Aplicar sobre la piel limpia.

Active Ingredients: ethylhexyl
methoxycinnamate 6,99 %

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.



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OPTIMAL TINTED COMPLEXION

ethylhexyl methoxycinnamate cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:24653-011

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
GLUCAMETACIN (UNII: N1EXE5EHAN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
NYLON-12 (UNII: 446U8J075B)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
LAUROYL LYSINE (UNII: 113171Q70B)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TOCOPHEROL (UNII: R0ZB2556P8)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
BENZYL BENZOATE (UNII: N863NB338G)	
PHENOXYETHANOL (UNII: HIE49ZZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24653-011-02	1 in 1 BOX		
1	NDC:24653-011-01	50 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/20/2012	

Labeler - Janssen Cosmetics GmbH (499187946)

Registrant - Janssen Cosmetics GmbH (499187946)

Establishment

Name	Address	ID/FEI	Business Operations
Janssen Cosmetics GmbH		499187946	manufacture(24653-011)

Revised: 9/2012

Janssen Cosmetics GmbH