

LONG LAST MAKE UP 02 (NEO HELIOPAN) - 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.

Drug Facts

Active Ingredients: ethylhexyl methoxycinnamate 6,0% Purpose: Sunscreen

Inactive Ingredients: Aqua [water], isohexadecane, cyclopentasiloxane, butylene glycol, tricaprylin, cetyl PEG/PPG-10/1 dimethicone, silica, cyclohexasiloxane, saccharide isomerate, dicaprylyl carbonate, polyglyceryl-4, isostearate, panthenol, lauroyl lysine, hydro-genated castor oil, disteardimonium hectorite, lecithin, ascorbylpalmitate, BHT, tocopherol, sodium chloride, cera microcristallina [microcrystalline wax], disodium EDTA, propylene carbonate, citric acid, parfum [fragrance], benzyl salicylate, hydroxyisohexyl 3-cyclohexene carboxaldehyde, hydroxycitronellal, limonene, alpha-isomethyl ionone, coumarin, linalool, phenoxyethanol, methylparaben, ethylparaben, propylparaben, butylparaben, isobutylparaben, CI 77 891 [titanium dioxide], CI 77491 [iron oxides], CI 77 492 [iron oxides], CI 77 499 [iron oxides]

Avoid contact with eyes.

Keep out of reach of children.

For External use only. Does not replace the use of sun products in case of sun exposure

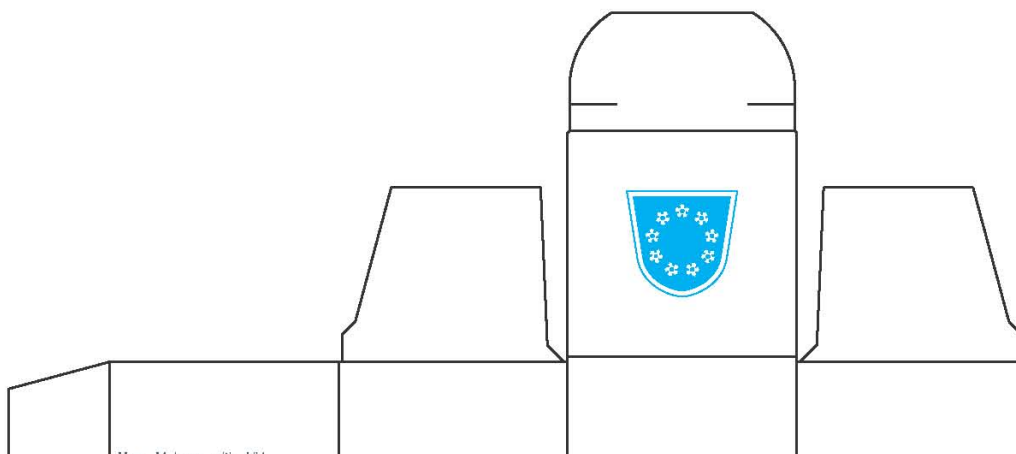
Discontinue use and consult a doctor if signs of rash or irritation develops and persists

Directions

Apply evenly onto cleansed skin, ideally on top of a day cream

Faltschachtel Spender Megaplast Mirco 30ml VK - #C-830
Druck: 2-farbig; Pantone 8920 / Pantone 431

150.50 mm



216.60 mm

use: makeup with UV Protection

Directions: Apply evenly onto cleansed skin, ideally on top of a day cream.

Active ingredients: ethylhexyl methoxycinnamate 6,0%
Other ingredients: Aqua [water], isohexadecane, cyclopentasiloxane, butylene glycol, tricaprylin, cetyl PEG/PPG-10/1 dimethicone, silica, cyclohexasiloxane, saccharide isomerate, dicaprylyl carbonate, polyglyceryl-4, isostearyl, panthenol, lauryl lysine, hydro-generated castor oil, disteardimonium hecortate, lecithin, ascorbylpalmitate, BHT, tocopherol, sodium chloride, cera microcrystallina [microcrystalline wax], disodium EDTA, propylene carbonate, citric acid, parfum [fragrance], benzyl salicylate, hydroxyisohexyl 3-cyclohexene carboxaldehyde, hydroxycitronellal, limonene, alpha-isomethyl ionone, coumarin, linalool, phenoxylethanol, methylparaben, ethylparaben, propylparaben, butylparaben, isobutylparaben, CI 77 891 [titanium dioxide], CI 77491 [iron oxides], CI 77 499 [iron oxides]

Warning: For external use only. Avoid contact with eyes. Discontinue use if signs of rash or irritation appears. Does not replace the use of sun products in case of sun exposure. Keep out of reach of children.

JANSSEN COSMETICS

52005 Aachen • Germany
www.janssen-cosmetics.com
Made in Germany • Ref.: C-830

JANSSEN COSMECEUTICAL

MAKE UP

Natürlich wirkendes Make-Up mit UV Schutz für jeden Hauttyp.
Nach der Tagespflege auftragen und gleichmäßig verteilen.

Natural looking make-up with UV protection for all skin types.
Apply onto daily care and distribute evenly.

Fond de teint naturel avec protection UV pour chaque type de peau.
Appliquez par-dessus la crème de jour et étalez uniformément.

Make up dal colore naturale con protezione UV per tutti i tipi di pelle.
Applicare dopo l'usuale crema da giorno.

Maquillaje de aspecto natural con protección UV para todos los tipos de piel.
Aplicar después de la crema de día y distribuir uniformemente.

Natuurlijke make-up met UV-bescherming voor alle Huidtypen.

Long Lasting Make Up SPF 10
Fond de Teint

NET 1.0 FL. OZ. 30 ml e



K:12755-1

Janssen Cosmeceutical
Make Up
Long Lasting Makeup SPF 10
Net 1.0 Fl. oz. 30ml



Make-Up mit UV Schutz.
Nach der Tagespflege auftragen.
Make-up with UV protection.
Apply onto daily care.
Fond de teint avec protection UV.
Appliquez par-dessus la crème de jour.

MAKE UP

**Long Lasting
Make Up
SPF 10**
Fond de Teint
Tenue Parfaite

NET 1.0 FL. OZ. 30 ml e

Make up con protezione UV.
Applicare dopo l'usuale crema da giorno.
Maquillaje con protección UV.
Aplicar después de la crema de día.
Make-up met UV-bescherming.
Op de dagcrème aanbrengen.

**Active Ingredients: Ethylhexyl
Methoxycinnamate 7.5%**

Warning: For external use only. Avoid contact with eyes. Discontinue use if signs of rash or irritation appears. Does not replace the use of sun products in case of sun exposure. Keep out of reach of children.



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Janssen Cosmeceutical
Make Up
Long Lasting Makeup SPF 10
Net 1.0 Fl oz. 30ml

LONG LAST MAKE UP 02 (NEO HELIOPAN)

ethylhexyl methoxycinnamate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24653-805
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6 mL in 30 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
ISOHEXADECANE (UNII: 918X10UF1E)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	

TRICAPRYLIN (UNII: 6P92858988)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
DIMETHICONE (UNII: 92RU3N3Y1O)
Silicon Dioxide (UNII: ETJ7Z6XBU4)
QUATERNIUM-18 (UNII: O7757NO1VL)
HECTORITE (UNII: 08X4KI73EZ)
SACCHARIDE ISOMERATE (UNII: W8K377W98I)
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)
LAUROYL LYSINE (UNII: 113171Q70B)
PANTHENOL (UNII: WV9CM0O67Z)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)
EDETATE DISODIUM (UNII: 7FLD91C86K)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
CITRIC ACID (UNII: 2968PHW8QP)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
BENZYL SALICYLATE (UNII: WAO5MKN9TU)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
IONONE (UNII: QP734LIN1K)
COUMARIN (UNII: A4VZ22K1WT)
LINALOOL, DL- (UNII: D81QY6I88E)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
METHYL PARABEN (UNII: A2I8C7HI9T)
ETHYL PARABEN (UNII: 14255EXE39)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
BUTYL PARABEN (UNII: 3QP1IU3FV8)
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24653-805-02	1 in 1 CARTON		
1	NDC:24653-805-01	30 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/10/2008	

Labeler - Janssen Cosmetics GmbH (499187946)

Registrant - Janssen Cosmeceutical LLC (052993438)

Establishment

Name	Address	ID/FEI	Business Operations
Janssen Cosmecetics GmbH		499187946	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Dr. Sacher Kosmetik GmbH		341926681	api manufacture

Revised: 1/2011

Janssen Cosmetics GmbH