

FLORMAR PERFECT COVERAGE FOUNDATION SUNSCREEN BROAD SPECTRUM SPF 15 103 CREAMY BEIGE- octinoxate cream

Kosan Kozmetik Sanayi ve Ticaret A.S.

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.

flormar PERFECT COVERAGE FOUNDATION CREAM SUNSCREEN BROAD SPECTRUM SPF 15 103 Creamy Beige

flormar PERFECT COVERAGE FOUNDATION CREAM SUNSCREEN BROAD SPECTRUM SPF 15 103 Creamy Beige

Active ingredient

Octinoxate 1%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only

Do not use

on damaged or broken skin

When using this product

keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

rash occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Shake well before use.
- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin

aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- ◦ Limit time in the sun, especially from 10 a.m. – 2 p.m.
- ◦ Wear long-sleeved shirts, pants, hats and sunglasses.
- Children under 6 months of age: Ask a doctor.

Other information

- Protect the product in this container from excessive heat and direct sun

Inactive ingredients

water, cyclopentasiloxane, isononyl isononanoate, diethylhexyl malate, butylene glycol, sorbitan olivate, HDI/trimethylol hexyllactone crosspolymer, cetyl PEG/PPG-10/1 dimethicone, hexyl laurate, magnesium aluminum silicate, glycerin, sweet almond (*Prunus amygdalus dulcis*) oil, polyglyceryl-4 isostearate, hydrogenated olive (*Olea europaea*) oil, phenoxyethanol, aluminum hydroxide, polyglyceryl-3 polydimethyl siloxyethyl dimethicone, triethoxycaprylylsilane, xanthan gum, dimethicone/vinyl dimethicone crosspolymer, olive (*Olea europaea*) fruit oil, stearic acid, bisabolol, fragrance, methylparaben, propylene glycol, olive (*Olea europaea*) oil unsaponifiables, PEG-8, silica, tocopherol, glyceryl acrylate/acrylic acid copolymer, ascorbyl palmitate, PVM/MA copolymer, ascorbic acid, citric acid, propylparaben, linalool, butylphenyl methylpropional, alpha-isomethyl ionone, citronellol, benzyl salicylate, citronellol, benzyl salicylate, geraniol, coumarin, titanium dioxide, iron oxides.

Product Labels



PERFECT COVERAGE

FOUNDATION CREAM
SUNSCREEN
BROAD SPECTRUM SPF 15

1.0 fl oz (30 ml)

Peel away for Drug Facts

Covers skin imperfections, makes skin appear smoother. A new cream formula with an impressive soft and rich texture for comfortable and long lasting make-up. A foundation which helps to make the skin appear healthy, hydrated and younger.

Shake well before use

Kosan Kozmetik Sanayi ve Ticaret A.S.

Gebze Organize Sanayi Bolgesi
Ihsan Dede Cad.900.SK NO:133
Gebze, Kocaeli 41480 Turkey

Made in Turkey

www.flormar.com

To report a serious adverse event contact [917] 768-7350.



Drug Facts

Active ingredient

Octinoxate 1%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions

- Shake well before use.
- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 a.m. – 2 p.m.
 - Wear long-sleeved shirts, pants, hats and sunglasses.
- Children under 6 months of age: Ask a doctor.

Other information

- Protect the product in this container from excessive heat and direct sun.

Drug Facts (continued)

Inactive ingredients water, cyclopentasiloxane, isononyl isononanoate, diethylhexyl maleate, butylene glycol, sorbitan olivate, HDI/trimethylol hexyllactone crosspolymer, cetyl PEG/PPG-10/1 dimethicone, hexyl laurate, magnesium aluminum silicate, glycerin, sweet almond (Prunus amygdalus dulcis) oil, polyglyceryl-4 isostearate, hydrogenated olive (Olea europaea) oil, phenoxyethanol, aluminum hydroxide, polyglyceryl-3 polydimethyl siloxyethyl dimethicone, triethoxycaprylylsilane, xanthan gum, dimethicone/vinyl dimethicone crosspolymer, olive (Olea europaea) fruit oil, stearic acid, bisabolol, fragrance, methylparaben, propylene glycol, olive (Olea europaea) oil unsaponifiables, PEG-8, silica, tocopherol, glyceryl acrylate/acrylic acid copolymer, ascorbyl palmitate, PVMMA copolymer, ascorbic acid, citric acid, propylparaben, linalool, butylphenyl methylpropional, alpha-isomethyl ionone, citronellol, benzyl salicylate, citronellol, benzyl salicylate, geraniol, coumarin, titanium dioxide, iron oxides.

FLORMAR PERFECT COVERAGE FOUNDATION SUNSCREEN BROAD SPECTRUM SPF 15 103 CREAMY BEIGE

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61722-082
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
DIETHYLHEXYL MALEATE (UNII: C2F7JHI12L)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	

MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
GLYCERIN (UNII: PDC6A3C0OX)
ALMOND OIL (UNII: 66YXD4DKO9)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
OLIVE OIL (UNII: 6UYK2W1W1E)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
XANTHAN GUM (UNII: TTV12P4NEE)
STEARIC ACID (UNII: 4ELV7Z65AP)
LEVOMENOL (UNII: 24WE03BX2T)
METHYL PARABEN (UNII: A2I8C7HI9T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
TOCOPHEROL (UNII: R0ZB2556P8)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
BENZYL SALICYLATE (UNII: WAO5MKN9TU)
GERANIOL (UNII: L837108USY)
COUMARIN (UNII: A4VZ22K1WT)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61722-082-00	1 in 1 BOX	07/06/2014	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/06/2014	

Labeler - Kosan Kozmetik Sanayi ve Ticaret A.S. (644090409)