

**FLORMAR PERFECT COVERAGE FOUNDATION SUNSCREEN BROAD SPECTRUM SPF 15 101 PASTELLE- 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.*

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**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, isomonyl 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.

**flormar PERFECT COVERAGE FOUNDATION CREAM SUNSCREEN BROAD SPECTRUM SPF 15 101 Pastelle 30ml (61722-080-00)**



## 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](http://www.flormar.com)

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



## Drug Facts

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### Purpose

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## Drug Facts (continued)

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- Reapply at least every 2 hours.
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  - Limit time in the sun, especially from 10 a.m. – 2 p.m.
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### Drug Facts (continued)

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## FLORMAR PERFECT COVERAGE FOUNDATION SUNSCREEN BROAD SPECTRUM SPF 15 101 PASTELLE

octinoxate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61722-080
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
DIETHYLHEXYL MALEATE (UNII: C2F7JHI2L)	
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:61722-080-00	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)