

**FLORMAR CC MAGICAL COLOR EFFECT COLOR CORRECTING CREAM SUNSCREEN
BROAD SPECTRUM SPF 15 CC04- 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 CC Cream Magical Color Effect Color Correcting Cream Sunscreen Broad Spectrum
SPF 15 CC04**

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Active Ingredient

Octinoxate 5%

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

- Wear alone or under foundation.
- Shake well before use.
- After use, close the cap properly.
- 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, butylene glycol, polysilicone-11, cetyl PEG/PPG-10/1 dimethicone, dimethicone, PEG- 10 dimethicone, betaine, polymethylsilsesquioxane, trimethylsiloxysilicate, disteardimonium hectorite, SD alcohol 40-B, phenolxyethanol, synthetic fluorophlogophite, glycerin, apricot (*Prunus armeniaca*) kernel oil, acrylate/ammonium methacrylate copolymer, isopropyl myristate, panthenol, sodium chloride, triethyl citrate, ethylhexylglycerin, fragrance, laureth-12, silica, aluminum hydroxide, triethoxycaprylsilane, pomegranate (*Punica granatum*) fruit extract, hexyl cinnamal, benzyl salicylate, butylphenyl methylpropional, alpha-isomethyl ionone, linalool, titanium dioxide, iron oxides.

Product Labels

This unit is packaged in an outer container. Please see outer container for complete drug facts information.



CC Cream
Magical Color Effect
Color Correcting Cream
Sunscreen
Broad Spectrum SPF 15

Illuminates the skin

CC04

Conceals problematic areas such as scar, marks, or areas that need extra coverage to help the skin appear more natural.

1.33 fl oz (40 ml)

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Active ingredient: Octinoxate 5%

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Kosan Kozmetik Sanayi ve Ticaret A.S.




Gebze Organize Sanayi Bölgesi
İhsan 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.



	<h3>Drug Facts</h3> <p>Active ingredient Purpose Octinoxate 5% Sunscreen</p> <p>Uses</p> <ul style="list-style-type: none"> 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. <p>Warnings</p> <p>For external use only</p> <p>Do not use on damaged or broken skin</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash occurs</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>		<h3>Drug Facts (continued)</h3> <p>Inactive ingredients water, cyclopentasiloxane, butylene glycol, polysiloxane-11, cetyl PEG/PPG-10/1 dimethicone, dimethicone, PEG-10 dimethicone, betaine, polymethylsilsesquioxane, trimethylsilyloxyethyl dimethylammonium hectorite, SD alcohol 40-B, phenylethanol, synthetic fluorophlogopite, glycerin, apricot (Prunus armeniaca) kernel oil, acrylate/ammonium methacrylate copolymer, isopropyl myristate, panthenol, sodium chloride, triethyl citrate, ethylhexylglycerin, fragrance, laureth-12, silica, aluminum hydroxide, triethoxycaprylsilane, pomegranate (Punica granatum) fruit extract, hexyl cinnamal, benzyl salicylate, butylphenyl methylpropional, alpha-isomethyl ionone, limonol, titanium dioxide, iron oxides</p>
<h2>CC Cream</h2> <h3>Magical Color Effect Color Correcting Cream Sunscreen Broad Spectrum SPF 15</h3>	<h3>Directions</h3> <ul style="list-style-type: none"> Wear alone or under foundation. Shake well before use. After use, close the cap properly. 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: <ul style="list-style-type: none"> 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. 	<h2>CC Cream</h2> <h3>Magical Color Effect Color Correcting Cream Sunscreen Broad Spectrum SPF 15</h3>	<p>Kosan Kozmetik Sanayi ve Ticaret A.S. Getze Organize Sanayi Bolgesi Ihsan Dede Cad.900.SK NO:133 Getze, Kocaeli 41480 Turkey</p> <p>Made in Turkey</p> <p>www.flormar.com</p>
<p>illuminates the skin</p> <p>CC04</p> <p>Conceals problematic areas such as scar, marks, or areas that need extra coverage to help the skin appear more natural.</p> <p>1.33 fl oz (40 ml)</p>	<p>Other information</p> <ul style="list-style-type: none"> Protect the product in this container from excessive heat and direct sun 	<p>illuminates the skin</p> <p>CC04</p> <p>Conceals problematic areas such as scar, marks, or areas that need extra coverage to help the skin appear more natural.</p> <p>1.33 fl oz (40 ml)</p>	<p>Conceals problematic areas such as scar, marks, or areas that need extra coverage to help the skin appear more natural. Hydrates and illuminates the skin and helps to provide the appearance of even-toned skin. Apply a light layer of CC Cream by rubbing on the skin. Wear alone or under foundation to get your unique hue. Shake well before use.</p> <p>Keep away from direct sunlight and keep in a cool place. After use, close the cap properly.</p> <p>To report a serious adverse event contact (917) 768-7350.</p> <p>ITEM:1236.00</p> 

FLORMAR CC MAGICAL COLOR EFFECT COLOR CORRECTING CREAM SUNSCREEN BROAD SPECTRUM SPF 15 CC04

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 1722-142
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	50 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THF5PC10R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BETAINE (UNII: 3SCV180C9W)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PANTHENOL (UNII: WV9CM0O67Z)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
LAURETH-12 (UNII: OAH19558U1)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61722-142-00	1 in 1 BOX	07/08/2014	
1		40 mL in 1 TUBE; 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	07/08/2014	

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

