

**FLORMAR CONCEALER SUNSCREEN BROAD SPECTRUM SPF 20 LC05 CAPPUCCINO-
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 Concealer Cream Sunscreen Broad Spectrum SPF 20 LC05 CAPPUCCINO

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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

- 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, dimethicone, butylene glycol, biosaccharide gum-4, PEG-10 dimethicone, polymethylsilsequioxane, disteardimonium hectorite, trimethylsiloxysilicate, glycerin, SD alcohol 40-B, phenoxyethanol, polysilicone-11, sodium chloride, sodium PCA, aluminum hydroxide, urea, alpha-glucan oligosaccharide, propanediol, triethoxycaprylylsilane, panthenol, mushroom (*Fomes officinalis*) extract, fragrance, ethylhexylglycerin, trehalose, leuconostoc/radish root ferment filtrate, algin, xanthan gum, polyquaternium-51, caprylyl glycol, hydrolyzed vegetable protein, sodium hyaluronate, pectin, arginine, proline, serine, glucose, carrageenan (*Chondrus crispus*), titanium dioxide, iron oxides.

**flormar Concealer Cream Sunscreen Broad Spectrum SPF 20 LC05 CAPPUCCINO 12ml
(61722-042-00)**

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



Concealer Cream
Sunscreen
Broad Spectrum SPF, 20

All Day Long Comfort

0.4 fl oz (12 ml)

FK

Active ingredient: Octinoxate 5%

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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.

Shake well before use



Drug Facts (continued)

Inactive ingredients

water, dimethicone, butylene glycol, biosaccharide gum-4, PEG-10 dimethicone, polymethylsilsequioxane, disteardimonium hectorite, trimethylsiloxysilicate, glycerin, SD alcohol 40-B, phenoxyethanol, polysilicone-11, sodium chloride, sodium PCA, aluminum hydroxide, urea, alpha-glucan oligosaccharide, propanediol, triethoxycaprylylsilane, panthenol, mushroom (Fomes officinalis) extract, fragrance, ethylhexylglycerin, trehalose, leuconostoc/radish root ferment filtrate, algin, xanthan gum, polyquaternium-51, caprylyl glycol, hydrolyzed vegetable protein, sodium hyaluronate, pectin, arginine, proline, serine, glucose, carrageenan (Chondrus crispus), titanium dioxide, iron oxides.

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

Exclusively high moisture-rich cream concealer provides flawless full coverage while helping the skin appear more firm. Shake well before use. After use, close the cap properly.

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

ITEM:1144.01



Concealer Cream
Sunscreen
Broad Spectrum SPF 20

All Day Long Comfort

0.4 fl oz (12 ml)

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| Active ingredient | Purpose |
|-------------------|-----------|
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FLORMAR CONCEALER SUNSCREEN BROAD SPECTRUM SPF 20 LC05 CAPPUCCINO

octinoxate cream

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61722-042 |
|-------------------------|----------------|--------------------|---------------|
| 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) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| UREA (UNII: 8W8T17847W) | |
| .ALPHA.-GLUCAN OLIGOSACCHARIDE (UNII: S95658MI3W) | |
| PROPANEDIOL (UNII: 5965N8W85T) | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | |
| PANTHENOL (UNII: WV9CM0O67Z) | |
| LARICIFOMES OFFICINALIS FRUITING BODY (UNII: 7IFM8431X3) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| TREHALOSE (UNII: B8WCK70T7I) | |
| LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458) | |
| SODIUM ALGINATE (UNII: C269C4G2ZQ) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| PECTIN (UNII: 89NA02M4RX) | |
| ARGININE (UNII: 94ZLA3W45F) | |
| PROLINE (UNII: 9DLQ4CIU6V) | |
| SERINE (UNII: 452VLY9402) | |
| DEXTROSE (UNII: IY9XDZ35W2) | |
| CARRAGEENAN (UNII: 5C69YCD2YJ) | |
| CHONDRUS CRISPUS (UNII: OQS23HUA1X) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:61722-042-00 | 1 in 1 BOX | 06/18/2014 | |
| 1 | | 12 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 | 06/18/2014 | |

