

PRETTY BY FLORMAR COVER UP FOUNDATION 001 PORCELAIN- 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.

Pretty by Flormar Cover up Foundation 001 Porcelain

Drug Facts

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.
- Keep the product cool.
- After use, close the tube properly with cap.

Inactive ingredients:

water, dimethicone, cyclopentasiloxane, butylene glycol, PEG-10 dimethicone, polymethylsilsesquioxane, trimethylsiloxysilicate, disteardimonium hectorite, SD alcohol 40-B, phenoxyethanol, glycerin, panthenol, sodium chloride, triethoxycaprylylsilane, polysilicone-11, aluminum hydroxide, fragrance, ethylhexylglycerin, fig (ficus carica) fruit extract, cotton (gossypium hirsutum) seed extract, linseed (linum usitatissimum) seed extract, may contain: titanium dioxide, iron oxides.

Package Labeling:

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COVER UP FOUNDATION

Peel away For Drug Facts

A new smooth texture glides on with a velvet soft feel and stays lightweight. High coverage with a pool of active ingredients including Cotton Extract and Panthenol helps reinforce the natural beauty of the skin.

Dermatologically tested.
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

To report a serious adverse event contact [971] 766-7350.


info@flormar.com.de

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12*38mm

Drug Facts	
Active ingredient	Purpose
Octinoxate 5%.....	Sunscreen
Uses	
<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. 	
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	
<ul style="list-style-type: none"> ■ 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. 	

Drug Facts (continued)
Other information
<ul style="list-style-type: none"> ■ Protect the product in this container from excessive heat and direct sun. ■ Keep the product cool. ■ After use, close the tube properly with cap.
Inactive ingredients : water, dimethicone, cyclopentasiloxane, butylene glycol, PEG-10 dimethicone, polymethylsilsesquioxane, trimethylsiloxysilicate, disteardimonium hectorite, SD alcohol 40-B, phenoxyethanol, glycerin, panthenol, sodium chloride, triethoxycaprylylsilane, polysilicone-11, aluminum hydroxide, fragrance, ethylhexylglycerin, fig (ficus carica) fruit extract, cotton (gossypium hirsutum) seed extract, linseed (linum usitatissimum) seed extract, may contain: titanium dioxide, iron oxides.

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COVER UP
FOUNDATION

SPF 15

1.0 fl oz (30ml e)

COVER UP FOUNDATION

A new smooth texture glides on with a velvet soft feel and stays lightweight. High coverage with a pool of active ingredients including Cotton Extract and Panthenol helps reinforce the natural beauty of the skin. Shake well before use.

Ingredients: Aqua(Water), Dimethicone, Cyclopentasiloxane, Ethylhexyl Methoxycinnamate, Butylene Glycol, PEG-10 Dimethicone, Polymethylsilsesquioxane, Trimethylsiloxysilicate, Distearidimonium Hectorite, Alcohol Denat., Phenoxyethanol, Glycerin, Panthenol, Sodium Chloride, Triethoxycaprylylsilane, Polysilicone-11, Aluminum Hydroxide, Parfum(Fragrance), Ethylhexylglycerin, Ficus Carica(Fig) Fruit Extract, Gossypium Hirsutum(Cotton) Seed Extract, Linum Usitatissimum(Linseed) Seed Extract. +/- (May Contain): CI 77891(Titanium Dioxide), CI 77492(Iron Oxides), CI 77491(Iron Oxides), CI 77499 (Iron Oxides). [0111112.00]

Kosan Koz. San. ve Tic. A.S.
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Madison Square Garden, 5 Penn Plaza, 23rd Floor,
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Flormar Cosmetics GmbH Schneiderstrasse 82
40764 Langenfeld, Germany



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[10*15mm](#)

01 PORCELAIN



PRETTY BY FLORMAR COVER UP FOUNDATION 001 PORCELAIN

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61722-305
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)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
GLYCERIN (UNII: PDC6A3C0OX)
PANTHENOL (UNII: WV9CM0O67Z)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
COTTON SEED (UNII: D10ZRJ0MXN)
FLAX SEED (UNII: 4110YT348C)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61722-305-00	1 in 1 BOX	06/17/2017	
1		30 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	06/17/2017		

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