

FLORMAR SMOOTH TOUCH FOUNDATION 12 AMBER- octinoxate aerosol
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 Smooth Touch Foundation 12 Amber

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, glycerin, trimethylsiloxysilicate, disteardimonium hectorite, SD alcohol 40-B, phenoxyethanol, sodium chloride, polysilicone-11, triethoxycaprylylsilane, aluminum hydroxide, sodium PCA, fragrance, urea, caprylic/capric triglyceride, ethylhexylglycerin, algae extract, soluble collagen, trehalose, leuconostoc/radish root ferment filtrate, polyquaternium-51, cymbidium grandiflorum flower extract, nelumbo nucifera flower extract, sodium hyaluronate, chlorphenesin, propylene glycol, fig (ficus carica) fruit extract, cotton (gossypium hirsutum) seed extract, linseed (linum usitatissimum seed extract, sodium dehydroacetate. may contain: titanium dioxide, iron oxides.

Package Labeling:



Peel away for Drug Facts
A new smooth texture creates flawless definition and dimension. A blend of lotus flower extract and orchid complex help reinforce the natural beauty of the skin.

Dermatologically tested.
Shake well before use.

Kosan Kozmetik Sanayi ve Ticaret A.Ş.,
Gebze Organize Sanayi Bölgesi
İhsan Dede Cad.900.SK NO:133
Gebze, Kocaeli 41480
Turkey
Made in Turkey

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

 343

www.flormar.com
info@flormar.com.de

Drug Facts	
Active ingredient	Purpose
Odinolate 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 or 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, glycerin, trimethylsiloxysilicate, disteardimonium hectorite, SD alcohol 40-B, phenoxyethanol, sodium chloride, polysilicone-11, triethoxycaprylylsilane, aluminum hydroxide, sodium PCA, fragrance, urea, caprylic/capric triglyceride, ethylhexylglycerin, algae extract, soluble collagen, trehalose, leuconostoc/radish root ferment filtrate, polyquaternium-51, cymbidium grandiflorum flower extract, nelumbo nucifera flower extract, sodium hyaluronate, chlorphenesin, propylene glycol, fig (ficus carica) fruit extract, cotton (gossypium hirsutum) seed extract, linseed (linum usitatissimum seed extract, sodium dehydroacetate. may contain: titanium dioxide, iron oxides.	

flormar

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.

www.flormar.com
 info@flormar.com.de
 ITEM: 1632.00

A new smooth texture creates flawless definition and dimension. A blend of lotus flower extract and orchid complex help reinforce the natural beauty of the skin.

Dermatologically tested. Shake well before use.

SMOOTH TOUCH FOUNDATION SPF 20

Sunscreen Broad Spectrum SPF 20

1.0 fl oz (30 ml e)

12 AMBER

Drug Facts

Active ingredient Purpose
 Octinoxate 5%.....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, glycerin, trimethylsiloxysilicate, disteardimonium hectorite, SD alcohol 40-8, phenoxyethanol, sodium chloride, polysilicone-11, triethoxycaprylylsilane, aluminum hydroxide, sodium PCA, fragrance, urea, caprylic/capric triglyceride, ethylhexylglycerin, algae extract, soluble collagen, trehalose, leuconostoc/radish root ferment filtrate, polyquaternium-51, cymbidium grandiflorum flower extract, nelumbo nucifera flower extract, sodium hyaluronate, chlorphenesin, propylene glycol, fig (ficus carica) fruit extract, cotton (gossypium hirsutum) seed extract, linseed (linum usitatissimum seed extract, sodium dehydroacetate, may contain: titanium dioxide, iron oxides.

FLORMAR SMOOTH TOUCH FOUNDATION 12 AMBER			
octinoxate aerosol			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 1722-28 1
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
UREA (UNII: 8W8T17847W)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TREHALOSE (UNII: B8WCK70T7I)	
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
CYMBIDIUM HOOKERIANUM FLOWER (UNII: H2DJ03DI5I)	
NELUMBO NUCIFERA FLOWER (UNII: 61W322NLDV)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FIG (UNII: TGD87RI2U)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61722-281-00	1 in 1 BOX	02/14/2016	
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	02/14/2016	

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

