

FLORMAR SOFT TOUCH FOUNDATION SUNSCREEN BROAD SPECTRUM SPF 20 ST04 MEDIUM BEIGE- 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 Soft Touch Foundation Cream Sunscreen Broad Spectrum SPF 20 ST04 Medium Beige

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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.
- 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, cyclopentasiloxane, butylene glycol, PEG-10 dimethicone, polymethylsilsesquioxane, trimethylsiloxysilicate, disteardimonium hectorite, glycerine, SD alcohol 40-B, phenoxyethanol, sodium chloride, polysilicone-11, triethoxycaprylylsilane, aluminum hydroxide, sodium PCA, Urea, fragrance, ethylhexylglycerin, algae extract, soluble collagen, trehalose, leuconostoc/radish root ferment filtrate, polyquaternium-51, sodium hyaluronate, chlorphenesin, propylene glycol, fig (*Ficus carica*) fruit extract, cotton (*Gossypium hirsutum*) seed extract, linseed (*Linum usitatissimum*) seed extract, sodium dehydroacetate, titanium dioxide, iron oxides.

Product Labels



**Soft Touch
Foundation Cream
Sunscreen
Broad Spectrum SPF 20**

Touch of Nature
Cream Silk Foundation

1.0 fl oz (30 ml)

Peel away for Drug Facts
Creamy and soft foundation instantly smoothes and stays perfectly flawless over time. Algae Extract, Soluble Collage, and other moisturizing ingredients help to make the complexion appear healthier and natural looking.

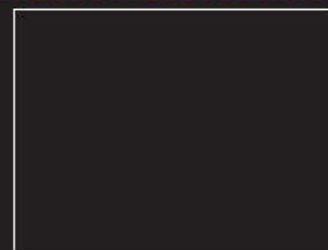
Shake well before use

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

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



Drug Facts

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Drug Facts (continued)

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octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61722-183
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)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
UREA (UNII: 8W8T17847W)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TREHALOSE (UNII: B8WCK70T7I)	
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FLAX SEED (UNII: 4110YT348C)	
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:61722-183-00	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)

Establishment

Name	Address	ID/FEI	Business Operations
Kosan Kozmetik Sanayi ve Ticaret A.S.		644090409	manufacture(61722-183)

Revised: 10/2019

Kosan Kozmetik Sanayi ve Ticaret A.S.