FLORMAR SMOOTH TOUCH FOUNDATION 01 PORCELAIN- 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 01 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 if 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:



Kosan Kozmetik Sanavi 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.

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pylysilicone-11, trifforopcopylysilisme, juminium
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octinoxate aerosol

Product Information

 $1.0 \, \mathrm{fl} \, \mathrm{oz} \, (30 \, \mathrm{ml} \, \bigcirc)$

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61722-270

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)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
DISTEARDIMO NIUM HECTORITE (UNII: X687XDK09L)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIMETHICO NE/VINYL DIMETHICO NE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
UREA (UNII: 8W8T17847W)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TREHALOSE (UNII: B8WCK70T7I)	
LEUCONOSTO C/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
CYMBIDIUM HOOKERIANUM FLOWER (UNII: H2DJ03DI5I)	
NELUMBO NUCIFERA FLOWER (UNII: 61W322NLDV)	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
CHLORPHENESIN (UNII: 1670 DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FIG (UNII: TGD87RII2U)	
SODIUM DEHYDRO ACETATE (UNII: 8 W46 YN971G)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

]	Packaging					
3	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
:	NDC:61722-270-00	1 in 1 BOX	02/11/2016			
:	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	0 2/11/20 16				

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

Revised: 10/2019 Kosan Kozmetik Sanayi ve Ticaret A.S.