# FLORMAR SMOOTH TOUCH FOUNDATION 03 LIGHT IVORY- 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.

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## Flormar Smooth Touch Foundation 03 Light Ivory

# **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:**











#### FLORMAR SMOOTH TOUCH FOUNDATION 03 LIGHT IVORY

octinoxate aerosol

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61722-272
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: 0 THT5PCI0 R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
DISTEARDIMO NIUM HECTO RITE (UNII: X687XDK09L)	
PHENOXYETHANOL (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 CARBO XYLATE (UNII: 469 OTG57A2)	
UREA (UNII: 8 W8 T178 47 W)	
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)	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
CHLORPHENESIN (UNII: 1670 DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FIG (UNII: TGD87RII2U)	
SO DIUM DEHYDRO ACETATE (UNII: 8 W46 YN9 71G)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging				
# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1 NDC:61722-272-00	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			

Kosan Kozmetik Sanayi ve Ticaret A.S.

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