FLORMAR SMOOTH TOUCH FOUNDATION 05 SOFT BEIGE- 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 05 Soft Beige

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.

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 Contro 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

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, SD alcohol 40-6, pnenoxyetnanol, sodium chloride, polysilicone-11, triethoxycaprylylsilane, aluminum hydroxide, sodium PCA, fragrance, urea, caprylic/capric triglyceride, ethylnexylglycerin, algae extract, soluble collagen, trehalose, leuconostoc/radish root ferment filtrate, polycuaternium-51, cymbidium grandiforum filtrate, polycuaternium-51, cymbidium grandiforum 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.



23 mm





Sunscreen **Broad Spectrum** SPF 20

05 SOFT BEIGE

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

Peel away for Drug Facts A new smooth texture creates flawless definition anddimension. 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.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 .

Drug Facts

Active ingredient Purpose Octinoxate 5%

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 cause

Warnings For external use only

Do not use on damaged or broken ski 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 swallowe get medical help or contact a Poison Conti Center right away.

Directions

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

■ Use a waller resistant sutta-uction a manning severaling.
■ Sun Protection Measures. Spending time in the sun increases your risk of skin canner and early skin aging. To decrease this risk, regularly use a sunscrean with a Broad Spectrum SPF value of 15 or hicher and other sun protection measures including:
■ Unit lime in the sun, secalarly from 10 a.m. – 2 p.m.
■ Wear brog-seved Shirts, parts, the ast or surfaces.
■ Children under 6 mortiles of ager. Ask a doctor.

Drug Facts (continued)

Other information

Protect the product in this container from excessive heat and direct sun. Keen the product cool After use, close the tube properly with cap

Inactive ingredients water,

dimethicone, cyclopentasiloxane, butylene glycol, dimethicone, polymethylsilsesquioxane, glycerin, trimethylsiloxysilicate, disteardimonium hectorite, trimethylsioxysiicate, disbaardimonium hectorie, 30 aloohiel 46 Benovyethand, solikum chloride, polysiicno-11, triethoxycaphylysilane, aluminum hydroxide, sodium PCA fraganace, urea, carylictap fribyecinide, ethylmizoylipycerin, algae extract, soluble collagen, trebalose, leuconostochradisch mod ferment filtert, polyysitemum-51, oymbidium gradifilorum filterte, polyysitemum-51, oymbidium gradifilorum filterte polysitemum-51, oymbidium gradifilorum filterte polysitemum-51, oymbidium gradifilorum filterte polysitemum-51, oymbidium gradifilorum folysitemum-61, observable polysitemum-61, oymbidium-61, nower extract, neumoù nuchera nower extract, socionn hyaluronate, chlorphenesin, propylene glycol, fig (ficus carica) fruit extract, cotton (gossypium hirsutum) seed extract, linseed (linum usitatissimum seed extract, sodii dehydroacetate. may contain: titanium dioxide, iron oxide

FLORMAR SMOOTH TOUCH FOUNDATION 05 SOFT BEIGE

octinoxate aerosol

Product Information

Product Type HUMAN OTC DRUG NDC:61722-274 Item Code (Source)

TOPICAL Route of Administration

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: 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)	
SO DIUM PYRROLIDONE CARBO XYLATE (UNII: 469 OTG57A2)	
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)	
HYALURONATE SO DIUM (UNII: YSE9 PPT4TH)	
CHLORPHENESIN (UNII: 1670 DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)	
FIG (UNII: TGD87RII2U)	
SODIUM DEHYDRO ACETATE (UNII: 8 W46 YN9 71G)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
FERRIC O XIDE RED (UNII: 1K09F3G675)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:61722-274-00	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	02/11/2016			

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

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