

FLORMAR REBORN FOUNDATION SUNSCREEN BROAD SPECTRUM SPF 20 SF07 NUDE 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 REBORN FOUNDATION CREAM SUNSCREEN BROAD SPECTRUM SPF 20 SF07 Nude 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 drop by drop with fingertips.
- 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.
- Wear long-sleeved shirts, pants, hats and sunglasses.

Other information

- Protect the product in this container from excessive heat and direct sun

Inactive ingredients

water, cyclopentasiloxane, butylene glycol, cetyl PEG/PPG-10/1 dimethicone, dimethicone, PEG-10 dimethicone, propanediol, polysilicone-11, glycerin, SD alcohol 40-B, dimethicone/vinyl dimethicone crosspolymer, phenoxyethanol, disteardimonium hectorite, trimethylsiloxysilicate, methyl methacrylate crosspolymer, sodium chloride, triethoxycaprylsilane, aluminum hydroxide, sodium PCA, ethylhexylglycerin, fragrance, urea, Anogeissus leiocarpus bark extract, algae extract, soluble collagen, silica, laureth-12, 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, caprylyl glycol, hexyl cinnamal, benzyl salicylate, butylphenyl methylpropional, alpha-isomethylionone, linalool, titanium dioxide, iron oxides.

Product Labels

This unit is packaged in an outer container. Please see outer container for complete drug facts information.



FOUNDATION CREAM SUNSCREEN
BROAD SPECTRUM SPF 20

1.0 fl oz (30 ml)

This unit is packaged in an outer container. Please see outer container for complete drug facts information.



FOUNDATION CREAM SUNSCREEN
BROAD SPECTRUM SPF 20

1.0 fl oz (30 ml)

Active ingredient: Octinoxate 5%

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.

Kosan Kozmetik Sanayi ve Ticaret A.Ş.

Gezce Organize Sanayi Bölgesi

İnsan Dede Cad. 900.SK NO:133

Gezce, Kocaeli 41480 Turkey

Made in Turkey

www.flormar.com

To report a serious adverse event contact (817) 766-7350.



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

This soft cream imparts a smooth-looking finish that stays perfectly flawless over time and helps to make the skin appear more firm and youthful. Also helps to hydrate the skin. Application: Shake well before use. Apply drop by drop with fingertips. Keep away from direct sunlight and keep in a cool place.

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

ITEM: 1302.00



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REBORN

FOUNDATION CREAM
SUNSCREEN
BROAD SPECTRUM SPF 20

1.0 fl oz (30 ml)

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.
- Apply drop by drop with fingertips.
- 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, cyclopentasiloxane, butylene glycol, cetyl PEG-PPG-10/1 dimethicone, dimethicone, PEG-10 dimethicone, propanediol, polysiloxane-11, glycerin, SD alcohol 40-8, dimethicone/vinyl dimethicone crosspolymer, phenoxethanol, disteardimonium hectorite, trimethylsiloxysilicate, methyl methacrylate crosspolymer, sodium chloride, trifluorocaprylsilane, aluminum hydroxide, sodium PCA, ethylhexylglycerin, fragrance, urea, Anogeissus leiocarpus bark extract, algae extract, soluble collagen, silica, laureth-12 trehalose, leucanostochadish 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, caprylyl glycol, hexyl cinnamal, benzyl salicylate, butylphenyl methylpropional, alpha-isomethyl ionone, linalool, titanium dioxide, iron oxides.

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REBORN

FOUNDATION CREAM
SUNSCREEN
BROAD SPECTRUM SPF 20

1.0 fl oz (30 ml)

FLORMAR REBORN FOUNDATION SUNSCREEN BROAD SPECTRUM SPF 20 SF07 NUDE BEIGE

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61722-202
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)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
DIMETHICONE (UNII: 92RU3N3Y1O)
PROPANEDIOL (UNII: 5965N8W85T)
GLYCERIN (UNII: PDC6A3C0OX)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
UREA (UNII: 8W8T17847W)
ANOGEISSUS LEOCARPUS BARK (UNII: U5TP1X38RH)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
LAURETH-12 (UNII: OAH19558U1)
TREHALOSE (UNII: B8WCK70T7I)
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
COTTON SEED (UNII: DI0ZRJ0MXN)
FLAX SEED (UNII: 4110YT348C)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)
BENZYL SALICYLATE (UNII: WAO5MKN9TU)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61722-202-00	1 in 1 BOX	07/04/2014	
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	07/04/2014	

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