

**FLORMAR REBORN BB SUNSCREEN BROAD SPECTRUM SPF 30 CP30 CARAMEL-  
octinoxate powder**

**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 REBORN BB SUNSCREEN BROAD SPECTRUM SPF 30 CP30 Caramel**

**Drug facts**

**Active Ingredient**

Octinoxate 5%

**Purpose**

sunscreen

**Uses**

- Helps prevent sunburn.
- If used as direct 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**

- Apply to face with a make-up sponge.
- 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**

neopentyl glycol diethylhexanoate, ethylhexyl palmitate, polyethylene, hydrogenated polysiobutene, isononyl isononanoate, octyldodecyl stearoyl stearate, aluminum starch octenyl succinate, candelilla (Candelilla cera) wax, pentaerythrityl tetrabenenate, isocetyl stearoyl stearate, jojoba (Simmondsia chinensis) seed oil, squalane, nylon-12, polyglyceryl-3 diisostearate, cyclopentasiloxane, polymethylsilsesquioxane, dimethicone/vinyl dimethicone crosspolymer, triethoxycaprylylsilane, aluminum hydroxide, fragrance, polyglyceryl-3 polydimethyl siloxyethyl dimethicone, silica, stearic acid, PEG-8, tocopherol, ascorbyl palmitate, ascorbic acid, citric acid, linalool, butylphenyl methylpropional, alpha-isomethyl ionone, citronellol, benzyl salicylate, geraniol, coumarin, titanium dioxide, iron oxides.

**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

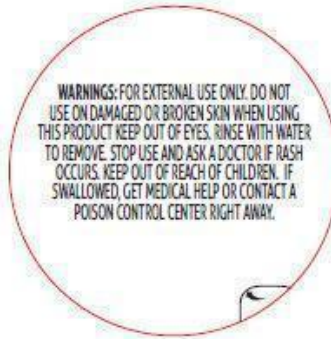
A Cream that creates the appearance of all day skin perfection with sensorial comfort. Extreme wearing, light texture adapts to the skin's movements with a medium to high covering film. Glides on with a velvet soft feel that stays lightweight, soft and smooth. application: Wash abd rinse your latex sponge when you are finished with your application. Before you put your latex sponge into the container, be sure that it is dried. Keep away from direct sunlight and keep in a cool place. After use, close the cap properly.

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

Flormar REBORN BB CREAM SUNSCREEN BROAD SPECTRUM SPF 30 Net Wt. 0.42 oz (12 g)

**Product Label**

<p>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</p> <p>A Cream that creates the appearance of all day skin perfection with sensorial comfort. Extreme wearing, light texture adapts to the skin's movements with a medium to high covering film. Glides on with a velvet soft feel that stays lightweight, soft and smooth. Application: Wash and rinse your latex sponge when you are finished with your application. Before you put your latex sponge into the container, be sure that it is dried. Keep away from direct sunlight and keep in a cool place. After use, close the cap properly.</p> <p>To report a serious adverse event contact [917] 768-7350.</p> <p>ITEM: 1304.00</p> 	  <p><b>REBORN</b></p> <p><b>BB CREAM</b></p> <p><b>SUNSCREEN BROAD SPECTRUM SPF 30</b></p> <p><b>Net Wt. 0.42 oz (12 g)</b></p>	<p><b>Drug Facts</b></p> <table border="1"> <tr> <td><b>Active ingredient</b></td> <td><b>Purpose</b></td> </tr> <tr> <td>Octinoxate 1%</td> <td>Sunscreen</td> </tr> </table> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>Helps prevent sunburn</li> <li>Used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.</li> </ul> <p><b>Warnings</b></p> <p>For external use only</p> <p>Do not use on damaged or broken skin</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash occurs</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>Apply to face with a make-up sponge.</li> <li>Apply liberally 15 minutes before sun exposure.</li> <li>Reapply at least every 2 hours.</li> <li>Use a water resistant sunscreen if swimming or sweating.</li> <li><b>Sun Protection Measures:</b> 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:       <ul style="list-style-type: none"> <li>Limit time in the sun, especially from 10 a.m. - 2 p.m.</li> <li>Wear long-sleeved shirts, pants, hats and sunglasses.</li> <li>Children under 6 months of age: Ask a doctor.</li> </ul> </li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>Protect the product in this container from excessive heat and direct sun</li> </ul> <p><b>Inactive ingredients</b> neopentyl glycol diethylhexanoate, ethylhexyl palmitate, polyethylene, hydrogenated polysiobutene, isononyl isononanoate, octyldodecyl stearoyl stearate, aluminum starch octenyl succinate, candelilla (Candelilla cera) wax, pentaerythrityl tetrabenenate, isocetyl stearoyl stearate, jojoba (Simmondsia chinensis) seed oil, squalane, nylon-12, polyglyceryl-3 diisostearate, cyclopentasiloxane, polymethylsilsesquioxane, dimethicone/vinyl dimethicone crosspolymer, triethoxycaprylylsilane, aluminum hydroxide, fragrance, polyglyceryl-3 polydimethyl siloxyethyl dimethicone, silica, stearic acid, PEG-8, tocopherol, ascorbyl palmitate, ascorbic acid, citric acid, linalool, butylphenyl methylpropional, alpha-isomethyl ionone, citronellol, benzyl salicylate, geraniol, coumarin, titanium dioxide, iron oxides.</p>	<b>Active ingredient</b>	<b>Purpose</b>	Octinoxate 1%	Sunscreen
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Octinoxate 1%	Sunscreen					



## FLORMAR REBORN BB SUNSCREEN BROAD SPECTRUM SPF 30 CP30 CAMEL

octinoxate powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61722-171
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 g

### Inactive Ingredients

Ingredient Name	Strength
NEOPENTYL GLYCOL DIETHYLHEXANOATE (UNII: U68ZV6W62C)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
OCTYLDODECYL STEAROYL STEARATE (UNII: 3D47Q6D93C)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
CANDELILLA WAX (UNII: WL0328HX19)	
PENTAERYTHRITYL TETRABEHENATE (UNII: 9MNZ044IRY)	
ISOCETYL STEAROYL STEARATE (UNII: IJV4LS383R)	
JOJOBA OIL (UNII: 724GKU717M)	
SQUALANE (UNII: GW89575KF9)	
NYLON-12 (UNII: 446U8J075B)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	

ASCORBIC ACID (UNII: PQ6CK8PD0R)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
BENZYL SALICYLATE (UNII: WAO5MNK9TU)
GERANIOL (UNII: L837108USY)
COUMARIN (UNII: A4VZ22K1WT)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61722-171-00	1 in 1 CARTON	10/24/2014	
1		12 g in 1 BOX; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/24/2014	

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

Revised: 10/2019

Kosan Kozmetik Sanayi ve Ticaret A.S.