FLORMAR REBORN BB SUNSCREEN BROAD SPECTRUM SPF 30 CP01 ROSE-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 BB SUNSCREEN BROAD SPECTRUM SPF 30 CP01 Rose

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 brokenskin

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 polyisobutene, isononyl isononanoate, octyldodecyl stearoyl stearate, aluminum starch octenyl succinate, candelilla (Candelilla cera) wax, pentaerythrityl tetrabehenate, 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 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. 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 Labels



Kosan Kozmetik Sanayi ve Ticaret A.S., Gebze Organize Sanayi Bolgesi Ihsan Dede Cad. 900. SK NO:133 Gebze, Kocael 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

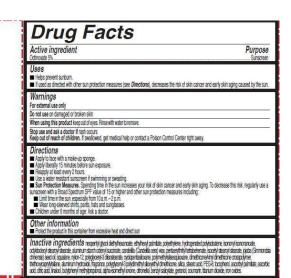
all day skin perfection with sensorial comfort. Extreme wearing, light teature adapts to the skin's movements with a medium to high covering film. Glides on with a velvet soft feel that stays lightweight, soft and smooth. Application. Wesh and insey our later, sorging when you are finished with your application. Before you put your later, sorgie into the container, be sure that it is dried. Keep away from direct sunlight and keep in a coot place. After use, close the cap properly.

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





Net Wt. 0.42 oz (12 g)



Enter section text here

FLORMAR REBORN BB SUNSCREEN BROAD SPECTRUM SPF 30 CP01 ROSE

octinoxate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61722-160
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	
NEO PENTYL GLYCOL DIETHYLHEXANO ATE (UNII: U68 ZV6 W62C)		
ETHYLHEXYL PALMITATE (UNII: 2865993309)		
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)		
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)		
OCTYLDODECYL STEAROYL STEARATE (UNII: 3D47Q6D93C)		
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19 PJ 0 O 6 2 9 4)		
CANDELILLA WAX (UNII: WL0328 HX19)		
PENTAERYTHRITYL TETRABEHENATE (UNII: 9MNZ044IRY)		
ISOCETYL STEAROYL STEARATE (UNII: IJV4LS383R)		
JOJOBA OIL (UNII: 724GKU717M)		
SQUALANE (UNII: GW89575KF9)		
NYLON-12 (UNII: 446 U8J075B)		
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46 P231IQV8)		
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)		
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		

TOCOPHEROL (UNII: R0 ZB2556 P8)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
LINALOOL, (+/-)- (UNII: D81QY6188E)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
ISOMETHYLALPHAIONONE (UNII: 9XP4LC555B)	
.BETACITRONELLOL, (R)- (UNII: P010UT964K)	
BENZYL SALICYLATE (UNII: WAO5MNK9TU)	
GERANIOL (UNII: L837108USY)	
COUMARIN (UNII: A4VZ22K1WT)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

]	Packaging			
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61722-160-00	1 in 1 BOX	07/06/2014	
1		12 g in 1 CONTAINER; 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	07/06/2014	

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

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