

FLORMAR REBORN DOUBLE RADIANCE PRIMER HIGHLIGHTER SUNSCREEN BROAD SPECTRUM SPF 10- 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.

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Active ingredient

Octinoxate 5%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

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

- Use all over face or to enlighten your chest area or shoulders.
- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.

- 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, isododecane, mica, butylene glycol, dimethicone, PEG-10 dimethicone, trimethylsiloxysilicate, polymethylsilsesquioxane, glycerin, phenoxyethanol, polysilicone-11, disteardimonium Hectorite, cetyl PEG/PPG-10/1 dimethicone, hexyl laurate, polyglyceryl-4 isostearate, sodium chloride, triethoxycaprylylsilane, propylene carbonate, ethylhexylglycerin, algae extract, disodium EDTA, fragrance, laureth-12, chlorphenesin, propylene glycol, tea (Camellia sinensis) leaf extract, maté (Ilex paraguariensis) leaf extract, guarana (Paullinia cupana) seed extract, sodium dextroacetate, titanium dioxide, iron oxides.

flormar REBORN DOUBLE RADIANCE PRIMER HIGHLIGHTER SUNSCREEN BROAD SPECTRUM SPF 10 30ml (61722-023-00)

This Unit Not Labeled For Retail Sale

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




DOUBLE RADIANCE PRIMER HIGHLIGHTER SUNSCREEN
BROAD SPECTRUM SPF 10

1.0 fl oz (30 ml)

 Kosan Kozmetik Sanayi ve Ticaret A.S.
Gebze Organize Sanayi Bölgesi
İhsan Dede Cad.900.SK NO:133
Gebze, Kocaeli 41480
Turkey
MADE IN TURKEY
www.flormar.com
To report a serious adverse event contact (917) 768-7350.

REF: 01110725.00

Active ingredient: Octinoxate 5%
Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
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:
■ Use all over face or to enlighten your décolleté or shoulders.
■ Apply liberally 15 minutes before sun exposure.
■ Reapply at least every 2 hours.
■ Use a water resistant sunscreen if swimming or sweating.
■ Children under 6 months of age: Ask a doctor.

A soft and lightweight texture that glides easily on skin for a long wearing look. Incredible bright effect with a luxurious sensorial texture. Highlight your complexion. Due to its exceptional skin adherence and ability to blend, it can be applied to illuminate cheekbones, chest area, or shoulders to provide a dazzling effect. Worn alone or over your foundation, it highlights and gives brilliant shimmers on your skin.

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 soft and lightweight texture that glides easily on skin for a long wearing look. Incredible bright effect with a luxurious sensorial texture. Highlight your complexion. Due to its exceptional skin adherence and ability to blend, it can be applied to illuminate cheekbones, chest area, or shoulders to provide a dazzling effect. Worn alone or over your foundation, it highlights and gives brilliant shimmers on your skin. Application: Use all over face or to enlighten your chest area and shoulders. Keep away from direct sunlight and keep in a cool place.

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



REBORN

DOUBLE RADIANCE PRIMER
HIGHLIGHTER SUNSCREEN
BROAD SPECTRUM SPF 10

1.0 fl oz (30 ml)

Drug Facts

Active ingredient	Purpose
Octinoxate 5%	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

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Stop use and ask a doctor if rash occurs

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Directions

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Other information

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Inactive ingredients

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REBORN

DOUBLE RADIANCE PRIMER
HIGHLIGHTER SUNSCREEN
BROAD SPECTRUM SPF 10

1.0 fl oz (30 ml)

FLORMAR REBORN DOUBLE RADIANCE PRIMER HIGHLIGHTER SUNSCREEN BROAD SPECTRUM SPF 10

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61722-023
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: 0THT5PCI0R)	
ISODODECANE (UNII: A8289P68Y2)	
MICA (UNII: V8A1AW0880)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIMETHICONE (UNII: 92RU3N3Y10)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LAURETH-12 (UNII: OAH19558U1)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
PAULLINIA CUPANA SEED (UNII: C21GE7524R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61722-023-00	1 in 1 BOX	06/16/2014	
1		30 mL in 1 JAR; 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	06/16/2014	

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

Revised: 10/2019

Kosan Kozmetik Sanayi ve Ticaret A.S.