

FLORMAR BLUR EFFECT BB SUNSCREEN BROAD SPECTRUM SPF 30 02 LIGHT MEDIUM- octinoxate, octocrylene, avobenzone 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 Blur Effect BB Cream Sunscreen Broad Spectrum SPF 30 02 Light Medium

Drug Facts

Active ingredient

Octinoxate 5%

Octocrylene 2 %

Avobenzone 1 %

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

- Wear alone or under foundation.
- Shake well before use.
- 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 30 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, cyclopentasiloxane, butylene glycol, polysilicone-11, cetyl PEG/PPG-10/1 dimethicone, dimethicone, PEG-10 dimethicone, trimethylsiloxysilicate, disteardimonium hectorite, synthetic fluorphlogopite, trimethylsiloxysilicate, SD alcohol 40-B, glycerin, dimethicone/vinyl dimethicone crosspolymer, phenoxyethanol, polyglyceryl-3 polydimethyl siloxyethyl dimethicone, polymethylsilsesquioxane, sodium chloride, stearic acid, silica, fragrance, ethylhexylglycerin, triethoxycaprylylsilane, magnesium stearate, aluminum hydroxide, algae extract, laureth-12, chlorophenesin, propylene glycol, camellia sinensis leaf extract, ilex paraguariensis leaf extract, paullinia cupana seed extract, sodium dehydroacetate. may contain: titanium dioxide, bismuth oxychloride, iron oxides.

Package Labeling:

The image shows the packaging for Flormar BB Cream. The background is a blue and white plaid pattern. At the bottom, there is a yellow banner with the text "BLUR EFFECT" and "BB Cream" in large yellow letters. The Flormar logo is visible in the center. A "Drug Facts" label is overlaid on the right side of the image, containing the following information:

Drug Facts

Active ingredient	Purpose
Octinoxate 5%.....	Sunscreen
Octocrylene 2%.....	Sunscreen
Avobenzone 1%.....	Sunscreen

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- Reapply at least every 2 hours.

Kosan Kozmetik Sanayi ve Ticaret A.S.,
 Gebze Organize Sanayi Bolgesi
 Ihsan Dede Cad.900.SK NO:133
 Gebze, Kocaeli 41480



FLORMAR BLUR EFFECT BB SUNSCREEN BROAD SPECTRUM SPF 30 02 LIGHT MEDIUM

octinoxate, octocrylene, avobenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61722-297
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
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	20 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
DIMETHICONE (UNII: 92RU3N3Y1O)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
GLYCERIN (UNII: PDC6A3C0OX)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
STEARIC ACID (UNII: 4ELV7Z65AP)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
MAGNESIUM STEARATE (UNII: 70097M6I30)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
LAURETH-12 (UNII: OAH19558U1)
CHLORPHENESIN (UNII: I670DAL4SZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)
PAULLINIA CUPANA SEED (UNII: C21GE7524R)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61722-297-00	1 in 1 BOX	08/02/2016	
1		35 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	08/02/2016	

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

Revised: 10/2019

Kosan Kozmetik Sanayi ve Ticaret A.S.