FLORMAR BB WHITE BW03 DARK MEDIUM- octinoxate, octocrylene, avobenzone aerosol 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 BB White Cream BW03 Dark Medium

Drug Facts

Active ingredients

Octinoxate 5%

Octinoxate 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.
- Childrenn 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, polysilicone-11, butylene glycol, cetyl PEG/PPG-10/1 dimethicone, PEG-10 dimethicone, trimethylsiloxysilicate, disteardimonium hectorite, SD alcohol 40-B, phenoxyethanol, polyglyceryl-3 polydimethyl siloxyethyl dimethicone, hydrolyzed vegetable flour, ascorbyl tetraisopalmitate, polymethylsilsesquioxane, sodium chloride, stearic acid, methyl methacrylate crosspolymer, silica, fragrance, ethylhexylglycerin, triethoxycaprylylsilane, aluminum hydroxide, laureth-12, caprylyl glycol, hexyl cinnamal benzyl salicylate, butylphenyl methylpropional, alphaisomethyl ionone,linalool, may contain: titanium dioxide, iron oxides.

Package Labeling:



WHITE CREAM

- UV protection
- Hydrates
- Corrects
- Illuminates
- Skin perfector
- Smoothes
- Conceals

SUNSCREEN **BROAD SPECTRUM SPF 30**

BW03 Dark Medium

1.33 fl oz (40ml€)

Drug Facts

Active ingredients **Purpose** Octinoxate 5% Sunscreen Octocrylene 2%. .Sunscreer Avobenzone 1%. .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

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, polysilicone-11, butylene glycol, cetyl PEG/PPG-10/1 dimethicone, PEG-10 dimethicone,

trimethylsiloxysilicate, disteardimonium hectorite, SD alcohol 40-B, phenoxyethanol,

polyglyceryl-3 polydimethyl siloxyethyl dimethicone, hydrolyzed vegetable flour, ascorbyl tetraisopalmitate, polymethylsilsesquioxane, sodium chloride, stearic acid, methyl methacrylate crosspolymer,

silica, fragrance, ethylhexylglycerin, triethoxycaprylylsilane, aluminum hydroxide, laureth-12, caprylyl glycol, hexyl cinnamal, benzyl salicylate, butylphenyl methylpropional, alphá-isométhyl ionone, linálool. máy contain: titanium dioxide, iron oxides.





- UV protection
- Hydrates
- Corrects
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SUNSCREEN BROAD SPECTRUM SPF 30

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

To report a serious adverse event contact [971] 766-7350.

www.flormar.com info@flormar.com.de









ITEM: 1382.00

SUNSCREEN BROAD SPECTRUM SPF 30

Dermatologically tested. Shake well before use.

Peel away for Drug Facts

Kosan Kozmetik Sanayi ve Ticaret A.S.,

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1.33 fl oz (40 ml€)

FLORMAR BB WHITE BW03 DARK MEDIUM

octinoxate, octocrylene, avobenzone aerosol

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:61722-292 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: 059QF0KO0R)		
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)		
DIMETHICO NE/VINYL DIMETHICO NE CROSSPO LYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
DISTEARDIMO NIUM HECTO RITE (UNII: X687XDK09L)		
PHENO XYETHANOL (UNII: HIE49 2ZZ3T)		
ASCORBYL TETRAISOPALMITATE (UNII: 47143LT58A)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)		
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)		
LAURETH-12 (UNII: O AH19558U1)		
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)		
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540 GJV69)		
ISOMETHYLALPHAIONONE (UNII: 9XP4LC555B)		
LINALOOL, (+/-)- (UNII: D81QY6I88E)		

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:61722-292-00	1 in 1 BOX	05/02/2016				
1	40 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	05/02/2016				

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

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