

FLORMAR PERFECT COVERAGE FOUNDATION 115 TOFFEE- 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 Perfect Coverage Foundation 115 Toffee

Drug Facts

Active ingredient

Octinoxate 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

- 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 cancer and early skin aging. To decrease this risk, regularly use 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.

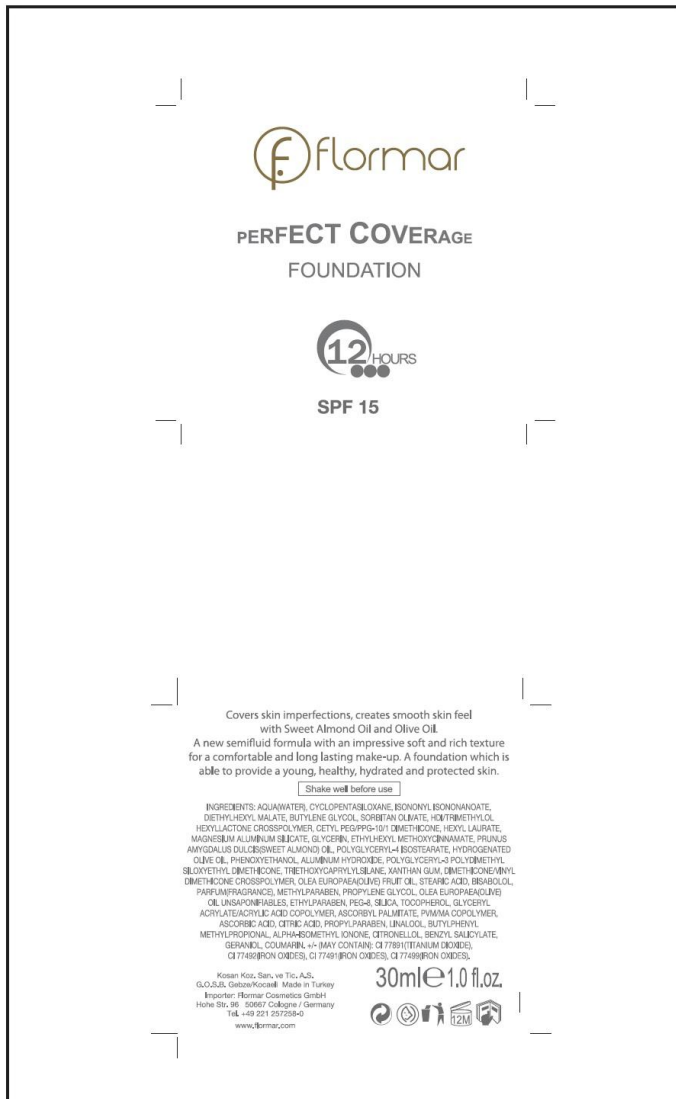
Other information

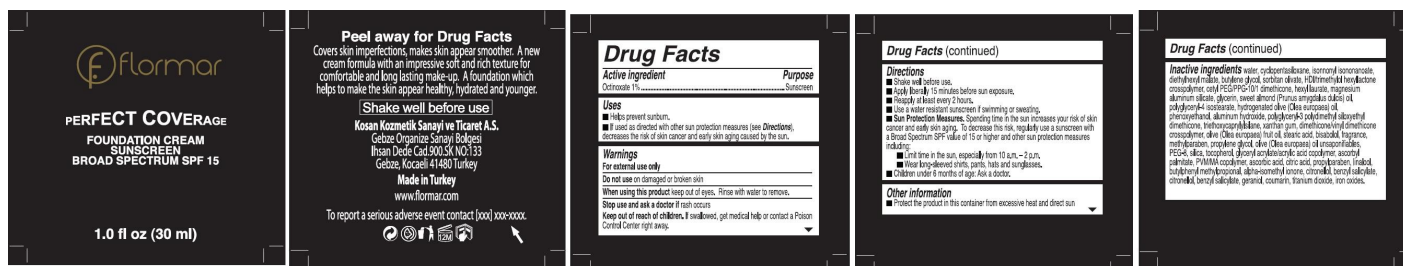
Protect this product in this container from excessive heat and direct sun

Inactive ingredients

water, cyclopentasiloxane, isononyl isononanoate, diethylhexyl malate, butylene glycol, sorbitan olivate, HDI/trimethylol hexylactone crosspolymer, cetyl PEG/PPG-10/1 dimethicone, hexyl laurate, magnesium aluminum silicate, glycerin, sweet almond (*Prunus amygdalus dulcis*) oil, polyglyceryl-4 isostearate, hydrogenated olive (*Olea europaea*) oil, phenoxyethanol, aluminum hydroxide, polyglyceryl-3 polydimethyl siloxyethyl dimethicone, triethoxycaprylylsilane, xanthan gum, dimethicone/vinyl dimethicone crosspolymer, olive (*Olea europaea*) fruit oil, stearic acid, bisabolol, fragrance, methylparaben, propylene glycol, olive (*Olea europaea*) oil unsaponifiables, PEG-8, silica, tocopherol, glyceryl acrylate/acrylic acid copolymer, ascorbyl palmitate, PVM/MA copolymer, ascorbic acid, citric acid, propylparaben, linalool, butylphenyl methylpropional, alpha-isomethyl ionone, citronellol, benzyl salicylate, citronellol, benzyl salicylate, geraniol, coumarin, titanium dioxide, iron oxides.

Package Labeling:





FLORMAR PERFECT COVERAGE FOUNDATION 115 TOFFEE

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61722-260
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ISO METHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
GERANIOL (UNII: L837108USY)	
COUMARIN (UNII: A4VZ22K1WT)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
WATER (UNII: 059QF0KO0R)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
DIETHYLHEXYL MALEATE (UNII: C2F7JHI12L)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
ALMOND OIL (UNII: 66YXD4DKO9)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
XANTHAN GUM (UNII: TTV12P4NEE)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
LEVOMENOL (UNII: 24WE03BX2T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61722-260-00	1 in 1 BOX	09/27/2015	
1		30 mL in 1 BOTTLE; 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	09/27/2015	

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

Revised: 10/2019

Kosan Kozmetik Sanayi ve Ticaret A.S.