

FLORMAR LIP MOISTURIZER CREAM CARMEL SUNSCREEN BROAD SPECTRUM SPF 15- octinoxate stick

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 Lip Moisturizer Cream Carmel Sunscreen Stick Broad Spectrum SPF 15

Drug Facts

Active ingredient

Octinoxate 6.8%

Purpose

Sunscreen

Use

- 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

- Apply on the lips. Reapply when lips are exposed to strong sun for protection.
- 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 this product in this container from excessive heat and direct sun

Inactive ingredients

DIISOSTEARYL MALATE, TRIDECYL TRIMELLITATE, OCTYLDODECANOL, HYDROGENATED POLYDECENE, PHENYL TRIMETHICONE, POLYETHYLENE, BIS-DIGLYCERYL POLYACYLADIPATE-2, TRIISOSTEARYL CITRATE, SILICA, MICROCRYSTALLINE WAX, MICA, CANDELILLA (EUPHORBIA CERIFERA) WAX, ZINC OXIDE, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, POLYMETHYL METHACRYLATE, PENTAERTHRITYL TETRABEHENATE, POLYBUTENE, SHEA (BUTYROSPERMUM PARKII) BUTTER, COCOA (THEOBROMA COCAO) SEED BUTTER, CASTOR (RICINUS COMMUNIS) SEED OIL, CAPRYLIC/CAPRIC TRIGLYCERIDE, LAUROYL LYSINE, FLAVOR, PEG-8, PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE, TOCOPHEROL, ORCHID (CYMBIDIUM GRANDIFLORUM) FLOWER EXTRACT, ASCORBYL PALMITATE, ASCORBIC ACID, CITRIC ACID, TITANIUM DIOXIDE, IRON OXIDES, D&C RED NO. 6., FD&C YELLOW NO.5 ALUMINUM LAKE.

Product Label

flormar
LIP MOISTURIZER CREAM
CARAMEL SUNSCREEN STICK
BROAD SPECTRUM SPF 15

KOSAN KOZMETİK SANAYİ VE TİCARET A.Ş.
GERZE ORGANİZE SANAYİ BÖLGESİ
İHSAN DEDE CAD.900.SK NO:133
GERZE, KOCAELİ 41480 TURKEY
MADE IN TURKEY
WWW.FLORMAR.COM
TO REPORT A SERIOUS ADVERSE EVENT
CONTACT (971) 766 - 7350.

THIS TRANSLUCENT AND BRIGHT
SPF 15 SUNSCREEN LIP
MOISTURIZER COMES WITH A
FRUITY AROMA TO GIVE YOUR LIPS
A FRESH AND GLOSSY LOOK. THIS
MOISTURIZING FORMULA HELPS
MAKE THE LIPS FEEL SUPPLE,
SMOOTH, AND SOFT. APPLY ON THE
LIPS. REAPPLY WHEN LIPS ARE
DRY.

**LIP
MOISTURIZER
CREAM
CARAMEL
SUNSCREEN
STICK**

flormar

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Drug Facts (continued)

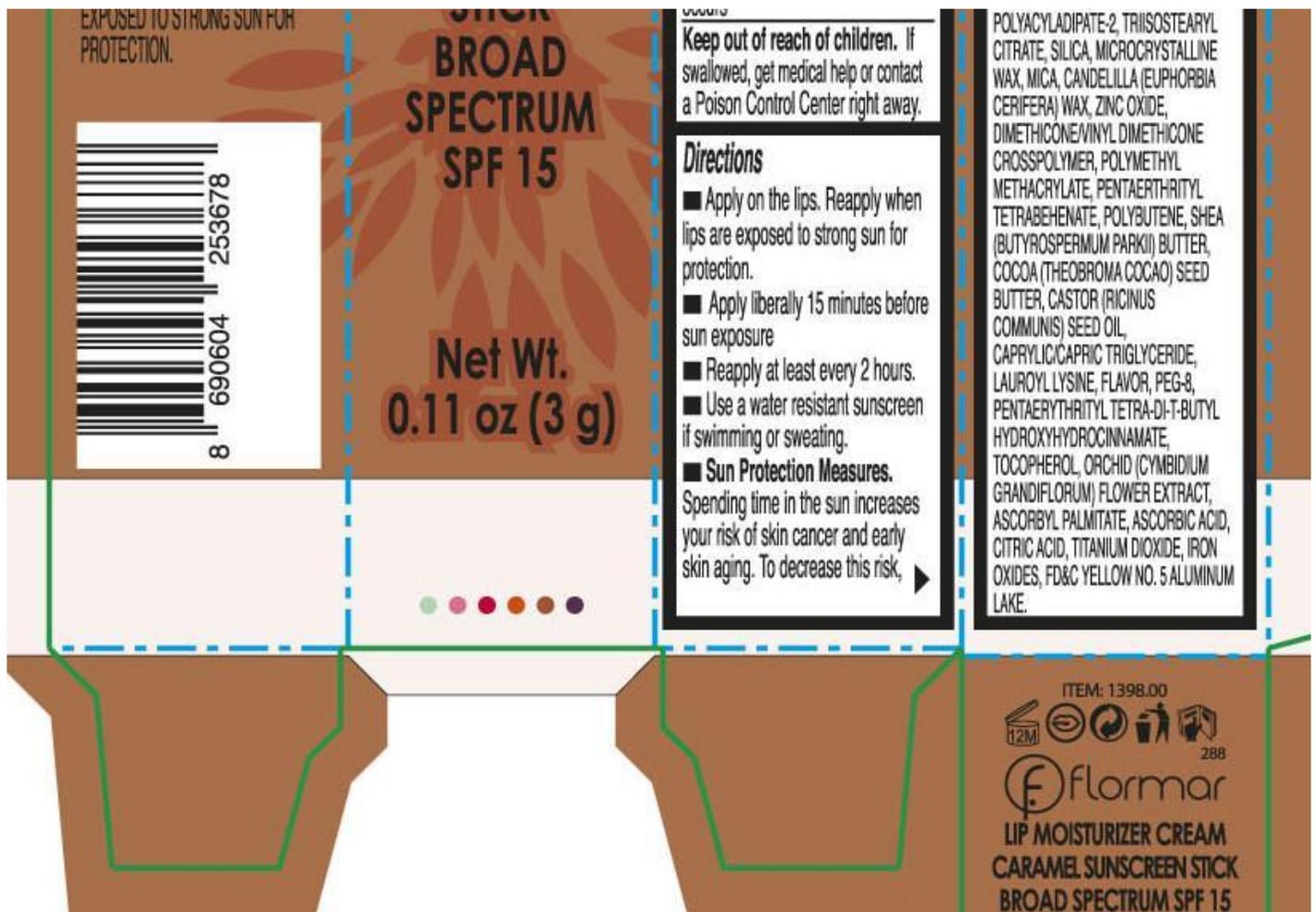
regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

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FLORMAR LIP MOISTURIZER CREAM CARAMEL SUNSCREEN BROAD SPECTRUM SPF 15

octinoxate stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61722-253
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	68 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
OCTYLDECANOL (UNII: 07UG7TSU58)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRISOSTEARYL CITRATE (UNII: 50XT325OOH)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
MICA (UNII: V8A1AW0880)
ZINC OXIDE (UNII: SOI2LOH54Z)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
LAUROYL LYSINE (UNII: 113171Q70B)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)
TOCOPHEROL (UNII: R0ZB2556P8)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
D&C RED NO. 6 (UNII: 481744A14O)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61722-253-00	1 in 1 BOX	01/30/2015	
1		3 g 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	01/30/2015	

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

Revised: 10/2019

Kosan Kozmetik Sanayi ve Ticaret A.S.