

**NEXT CELL MEDICAL SOOTHING COMPLEX- calming lotion broad spectrum spf 25
sunscreen lotion**

OMP, Inc.

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.

OBAGI MEDICAL SOOTHING COMPLEX

Calming Lotion

Broad Spectrum SPF 25 Sunscreen

Drug Facts

Active Ingredient

Titanium dioxide 4.80%

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 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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure

- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- **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: Ask a doctor

Other information

- store at controlled room temperature: 15°C–25°C (59°F–77°F)
- protect this product from excessive heat and direct sun

Inactive Ingredients

aqua (water), caprylic/capric triglyceride, glycerin, octyldodecyl stearoyl stearate, cyclopentasiloxane, butyloctyl salicylate, cyclohexasiloxane, butyrospermum parkii (shea) butter, cetyl alcohol, propanediol, sodium stearoyl glutamate, polyhydroxystearic acid, ranunculus ficaria extract, cetearyl glucoside, dimethicone, phytonadione, ananas sativus (pineapple) fruit juice, cetearyl alcohol, methylcellulose, microcrystalline cellulose, glyceryl stearate, aluminum stearate, sorbitan stearate, alumina, benzyl alcohol, iron oxides, aloe barbadensis leaf extract, benzoic acid, cellulose gum, disodium EDTA, butylene glycol, bioflavonoids, allantoin, chondrus crispus (carrageenan), sorbic acid, sodium hydroxide, phenoxyethanol, bromelain, camellia sinensis leaf extract, brassica oleracea italica (broccoli) extract, chamomilla recutita (matricaria) flower extract, cucumis sativus (cucumber) fruit extract, sodium hyaluronate, glucose, xanthan gum, sodium benzoate, honey extract, boswellia serrata extract, aspalathus linearis (rooibos) leaf extract, tetrapeptide-14

Questions or comments?

1.800.636.7546

Monday–Friday 9 a.m.–4 p.m. Pacific Time

Principal Display Panel – 47 mL Label

OBAGI MEDICAL

SOOTHING COMPLEX

Calming Lotion

Broad Spectrum SPF 25 Sunscreen

BY **SUZAN OBAGI MD**



1.6 fl.oz. (47 mL)

Soothing Complex Calming Lotion is a lightweight formula suitable for dry, delicate skin. With soothing and hydrating ingredients like sodium hyaluronate and aloe, the lightly tinted formula helps to blur minor imperfections and adapts to a range of skin tones and complexions. Broad Spectrum SPF 25 sunscreen provides physical UVA and UVB protection.

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Drug Facts (continued)

(cucumber) fruit extract, sodium hyaluronate, glucose, xanthan gum, sodium benzoate, honey extract, boswellia serrata extract, aspalathus linearis (rooibos) leaf extract, tetrapeptide-14

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OBAGI[®]
MEDICAL

SOOTHING COMPLEX

Calming Lotion
Broad Spectrum SPF 25 Sunscreen

BY SUZANOBAGI MD



nextcell[®]
MEDICAL

Distributed by Obagi Medical Products, a division of Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807
Manufactured for Nextcell Medical - Pittsburgh, PA 1.800.636.7546

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1.6 fl. oz. (47 mL)



NEXT CELL MEDICAL SOOTHING COMPLEX

calming lotion broad spectrum spf 25 sunscreen lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-602
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	480 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTYLDODECYL STEAROYL STEARATE (UNII: 3D47Q6D93C)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SHEA BUTTER (UNII: K49155WL9Y)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PROPANEDIOL (UNII: 5965N8W85T)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
RANUNCULUS FICARIA (UNII: YO2M043F0W)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHYTONADIONE (UNII: A034SE7857)	
PINEAPPLE JUICE (UNII: O4KOG0B1KC)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
METHYLCELLULOSE (1500 MPA.S) (UNII: P0NTE48364)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ALUMINUM MONOSTEARATE (UNII: P9BC99461E)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
ALUMINUM OXIDE (UNII: LM26O6933)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
FERROUS OXIDE (UNII: G7036X8B5H)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CITRUS BIOFLAVONOIDS (UNII: BD70459I50)	
ALLANTOIN (UNII: 344S277G0Z)	

CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78)
SORBIC ACID (UNII: X045WJ989B)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
BROMELAINS (UNII: U182GP2CF3)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
BROCCOLI SPROUT (UNII: 128UH9LOAE)
CHAMOMILE (UNII: FGL3685T2X)
CUCUMBER (UNII: YY7C30VXJT)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)
XANTHAN GUM (UNII: TTV12P4NEE)
SODIUM BENZOATE (UNII: OJ245FE5EU)
HONEY (UNII: Y9H1V576FH)
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)
ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU)
TETRAPEPTIDE-4 (UNII: S9N5X165MO)

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-602-15	47 mL in 1 TUBE; Type 0: Not a Combination Product	02/05/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/05/2018	

Labeler - OMP, Inc. (790553353)

Registrant - Valeant Pharmaceuticals North America LLC (042230623)

Establishment

Name	Address	ID/FEI	Business Operations
G.S. Cosmeceutical USA, Inc.		017014734	MANUFACTURE(62032-602)