

OBAGI MEDICAL PHYSICAL DEFENSE BROAD SPECTRUM MINERAL SUNSCREEN SPF 50 BY SUZANOBAGIMD- titanium dioxide and zinc oxide cream

Obagi Cosmeceuticals LLC

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 Physical Defense Broad Spectrum Mineral Sunscreen SPF 50 by SUZANOBAGIMD

Drug Facts

Active Ingredients

Titanium Dioxide 5.8%	Sunscreen
Zinc Oxide 14.4%	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 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 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a physician

Inactive Ingredients

Water (Aqua), Caprylic/Capric Triglyceride, Dicaprylyl Carbonate, Glycerin, Cetearyl Alcohol, Dimethicone, Propanediol, Polyhydroxystearic Acid, Cetearyl Glucoside, Aloe Barbadensis Leaf Extract, Brassica Oleracea Italica (Broccoli) Extract, Bioflavonoids, Dipotassium Glycyrrhizate, Polyglyceryl- 2, Dipolyhydroxystearate, Sodium Stearoyl Glutamate, Sodium C14-16 Olefin Sulfonate Stearic Acid, Lauryl Glucoside, Triethoxycaprylylsilane, Xanthan Gum, Silica, Alumina, Caprylhydroxamic Acid, Disodium EDTA, Caprylyl Glycol, Phenoxyethanol, Iron Oxides (CI 77491, CI 77492, CI 77499)

Other Information

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

Questions or comments?

1.800.636.7546

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

Distributed by Obagi Cosmeceuticals LLC,
Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - 96.3 g Tube Carton

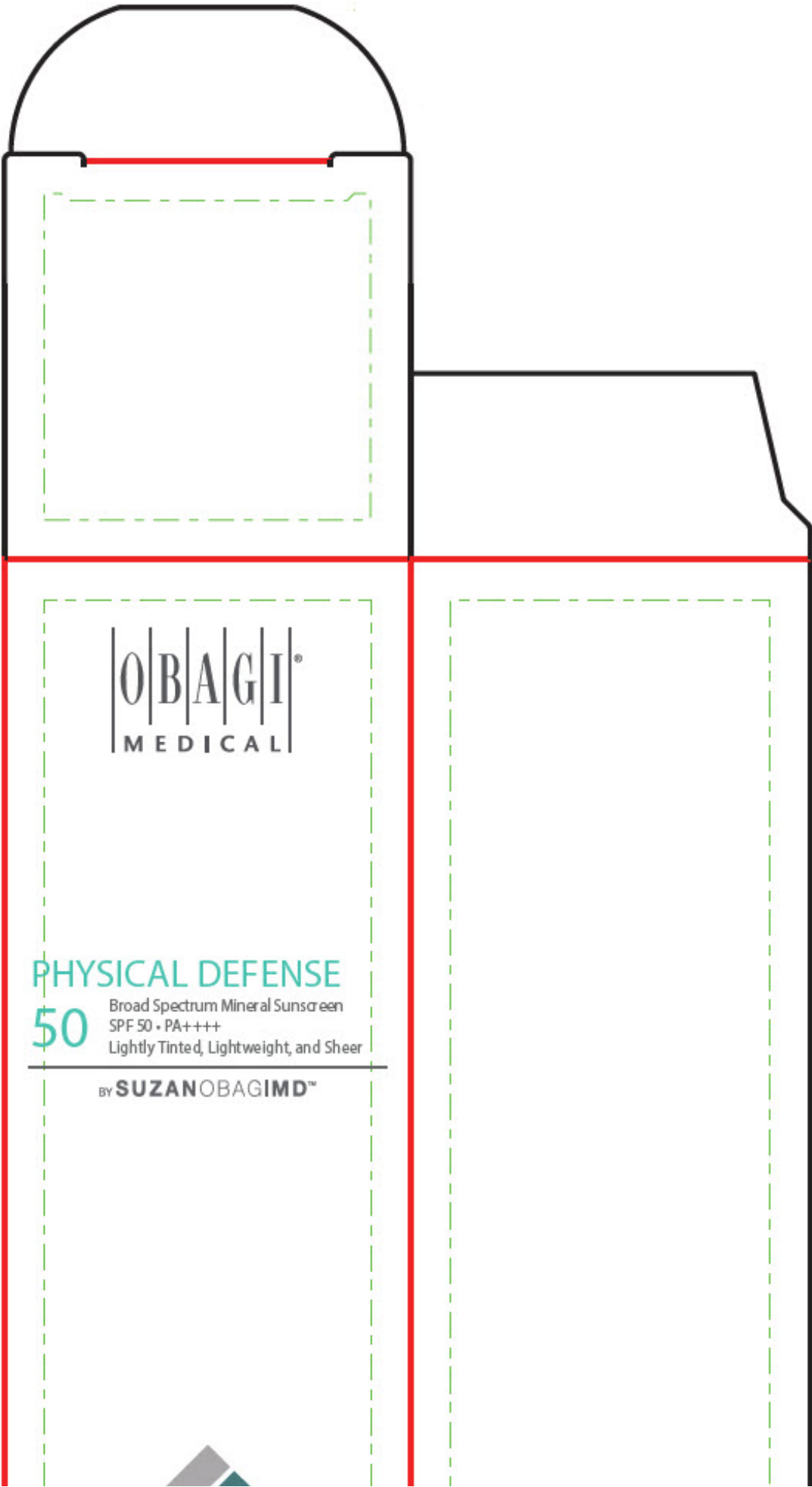
OBAGI®
MEDICAL

PHYSICAL DEFENSE
50 Broad Spectrum Mineral Sunscreen
SPF 50 • PA++++
Lightly Tinted, Lightweight, and Sheer

BY SUZANOBAGIMD™

HEV • VIS • IR Protection

Net wt. 3.4 oz. (96.3 g)



O|B|A|G|I|
MEDICAL

PHYSICAL DEFENSE

50

Broad Spectrum Mineral Sunscreen
SPF 50 • PA++++
Lightly Tinted, Lightweight, and Sheer

BY SUZANOBAGIMD™





HEV • VIS • IR Protection

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Physical Defense Broad Spectrum SPF 50 PA++++ utilizes minerals Titanium Dioxide & Zinc Oxide for UVA and UVB protection and provides fortified defense with a powerful combination of antioxidants to help offset free radicals. This sunscreen shields the skin from high energy visible light (HEV), visible light (VIS), infrared radiation (IR), all known to accelerate the skin aging process.

Physical Defense SPF 50 is lightly tinted with iron oxides, designed for a wide range of skin tones and complexions. It has been formulated without chemical sunscreen agents, parabens, synthetic fragrances and dyes, is lightweight, and provides sheer coverage. This formula has been dermatologist tested, is hypoallergenic, non-sensitizing, and developed for most skin types.

Drug Facts

Active Ingredients

Titanium Dioxide 5.8%Sunscreen
Zinc Oxide 14.4%Sunscreen

Drug Facts (continued)

Lauryl Glucoside, Triethoxycaprylylsilane, Xanthan Gum, Silica, Alumina, Caprylhydroxamic Acid, Disodium EDTA, Caprylyl Glycol, Phenoxyethanol, Iron Oxides (CI 77491, CI 77492, CI 77499)

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

Glues

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nextcell[®]
MEDICAL

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Long Beach, CA 90806
Manufactured for Nextcell Medical - Pittsburgh, PA
1.800.636.7546

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OBAGI MEDICAL PHYSICAL DEFENSE BROAD SPECTRUM MINERAL SUNSCREEN SPF 50 BY SUZANOBAGIMD

titanium dioxide and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-608
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	58 mg in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	144 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Dicaprylyl Carbonate (UNII: 609A3V1SUA)	
Glycerin (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
Dimethicone (UNII: 92RU3N3Y1O)	
Propanediol (UNII: 5965N8W85T)	
Cetearyl Glucoside (UNII: 09FUA47KNA)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
Broccoli (UNII: UOI4FT57BZ)	
CITRUS BIOFLAVONOIDS (UNII: BD70459I50)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
Sodium Stearoyl Glutamate (UNII: 65A9F4P024)	
Lauryl Glucoside (UNII: 76LN7P7UCU)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Xanthan Gum (UNII: TTV12P4NEE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
Caprylhydroxamic Acid (UNII: UPY805K99W)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-608-35	1 in 1 CARTON	04/01/2020	
1		96.3 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 FINAL	part352	04/01/2020	

Labeler - Obagi Cosmeceuticals LLC (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
G.S.COSMECEUTICAL USA		017014734	MANUFACTURE(62032-608)

Revised: 5/2021

Obagi Cosmeceuticals LLC