

**NU-DERM SYSTEM NORMAL-DRY SKIN TRANSFORMATION TRIAL-
hydroquinone, homosalate, octisalate, and zinc oxide
OBAGI COSMECEUTICAL LLC**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

OBAGI NU-DERM® SYSTEM

OBAGI NU-DERM®

Rx only

For external use only

DESCRIPTION

Hydroquinone, USP 4% is 1, 4-benzenediol. The drug is freely soluble in water and in alcohol. Chemically, hydroquinone is designated as p-dihydroxybenzene; the empirical formula is $C_6H_6O_2$; molecular weight is 110.11 g/mol. The chemical structure is in the diagram below.



Each gram of Obagi Nu-Derm® Clear contains:

ACTIVE: Hydroquinone, USP 4% (40 mg/g)

INACTIVES: ascorbic acid, BHT, butylparaben, cetyl alcohol, disodium EDTA, glycerin, lactic acid, methylparaben, propylparaben, saponins, sodium lauryl sulfate, sodium metabisulfite, stearyl alcohol, tocopheryl acetate, water (aqua)

Each gram of Obagi Nu-Derm Blender® contains:

ACTIVE: Hydroquinone, USP 4% (40 mg/g)

INACTIVES: ascorbic acid, BHT, cetyl alcohol, disodium EDTA, glycerin, lactic acid, methylparaben, phenyl trimethicone, PPG-2 myristyl ether propionate, propylparaben, saponins, sodium lauryl sulfate, sodium metabisulfite, TEA-salicylate, tocopheryl acetate, water (aqua)

Each gram of Obagi Nu-Derm® Sunfader® contains:

ACTIVES: Hydroquinone, USP 4% (40mg/g); Octinoxate, USP 7.5%; Oxybenzone, USP 5.5%

INACTIVES: ascorbic acid, BHT, butylparaben, cetyl alcohol, disodium EDTA, glycerin, methylparaben, propylparaben, saponins, sodium lauryl sulfate, sodium metabisulfite, stearyl alcohol, tocopheryl acetate, water (aqua)

CLINICAL PHARMACOLOGY

Topical application of hydroquinone produces a reversible depigmentation of the skin by inhibition of the enzymatic oxidation of tyrosine to 3, 4-dihydroxyphenylalanine (DOPA) and suppression of other melanocyte metabolic processes. Exposure to sunlight or ultraviolet light will cause repigmentation of the bleached areas, which may be prevented by the use of sunscreen agents such as those contained in Obagi Nu-Derm Sunfader[®] and Obagi Nu-Derm[®] Sun Shield Matte Broad Spectrum SPF 50.

INDICATIONS AND USAGE

For the gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentigines and other unwanted areas of melanin hyperpigmentation.

CONTRAINDICATIONS

People with prior history of sensitivity or allergic reaction to this product or any of its ingredients should not use it. The safety of topical hydroquinone use during pregnancy or in children (12 years and under) has not been established.

WARNINGS

Hydroquinone is a skin-bleaching agent, which may produce unwanted cosmetic effects if not used as directed. The physician should be familiar with the contents of this insert before prescribing or dispensing this product.

Test for skin sensitivity before using by applying a small amount to an unbroken patch of skin and check within 24 hours. Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor. Close patient supervision is recommended.

WARNINGS: Avoid contact with eyes, nose, mouth and lips. In case of accidental contact, patient should rinse thoroughly with water and contact a physician. Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight exposure sustains melanocytic activity.

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

PRECAUTIONS

(also see WARNINGS):

Treatment should be limited to relatively small areas of the body at one time since some patients experience a transient skin reddening and a mild burning sensation, which does not preclude treatment.

PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with topical hydroquinone. It is also not known whether hydroquinone can cause fetal harm when used topically on a pregnant woman or affect reproductive capacity. It is not known to what degree, if any, topical hydroquinone is absorbed systemically. Topical hydroquinone should be used on pregnant women only when clearly indicated.

NURSING MOTHERS

It is not known whether topical hydroquinone is absorbed or excreted in human milk. Caution is advised when topical hydroquinone is used by a nursing mother.

PEDIATRIC USAGE

Safety and effectiveness in children below the age of 12 years have not been established.

ADVERSE REACTIONS

No systemic adverse reactions have been reported. Occasional hypersensitivity (localized contact dermatitis) may occur, in which case the product should be discontinued and the physician notified immediately.

To report SUSPECTED ADVERSE REACTIONS, contact Obagi Cosmeceuticals LLC, at 1-800-636-7546 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

A thin application should be applied once or twice daily or as directed by a physician. If no improvement is seen after three (3) months of treatment, use of this product should be discontinued. Sun exposure should be limited by using a sunscreen agent or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

HOW SUPPLIED

Obagi Nu-Derm® Clear is available as follows:

Net wt. 2 oz. (57 g) bottle

NDC 62032-101-36

Obagi Nu-Derm Blender® is available as follows:

Net wt. 2 oz. (57 g) bottle

NDC 62032-100-36

Net wt. 1 oz. (28 g) bottle


NDC 62032-100-10

Obagi Nu-Derm Sunfader® is available as follows:

Net wt. 2 oz. (57 g) bottle

NDC 62032-116-36

Store at controlled room temperature: 15° to 25°C (59° to 77°F). Keep out of direct sunlight.

 **1-800-636-7546**

Manufactured for:

Obagi Cosmeceuticals LLC,

Long Beach, CA 90806

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Revised 01/2019

9458404

Obagi Nu-Derm® Clear (Hydroquinone, USP 4%) Skin Bleaching Cream

Obagi Nu-Derm Blender® (Hydroquinone, USP 4%) Skin Bleaching Cream

Obagi Nu-Derm Sunfader® (Hydroquinone, USP 4%; Octinoxate, USP 7.5%; Oxybenzone, USP 5.5%) Skin Bleaching Cream with Sunscreens

Sun Shield Matte Broad Spectrum SPF 50

Net wt. 1 oz. (28 g) AM

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Zinc Oxide 16.5%	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

Stop use and ask a doctor if rash occurs

When using this product keep out of eyes. Rinse with water to remove.

Keep out of reach of children. If 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

Water (Aqua), C15-19 Alkane, Octyldodecyl Neopentanoate, Polymethylsilsesquioxane, Sorbitan Olivatate, Silica, Polyglyceryl-6 Polyricinoleate, Sodium Chloride, Xanthan Gum, Glycerin, Hydroxyacetophenone, Disodium EDTA, 1,2-Hexanediol, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylsilane, Polyhydroxystearic Acid, Distearidimonium Hectorite, Polyglyceryl-2 Isostearate, Euphorbia Cerifera (candelilla) Wax, Beeswax, Dimethicone

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 - Kit Carton

NDC# 62032-532-07

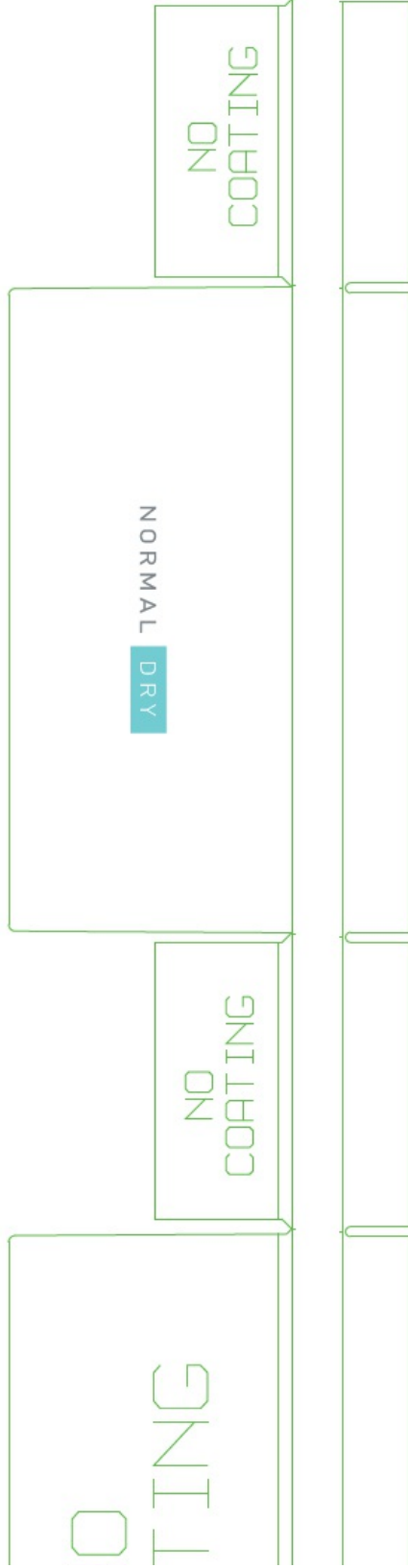
OBAGI®
MEDICAL

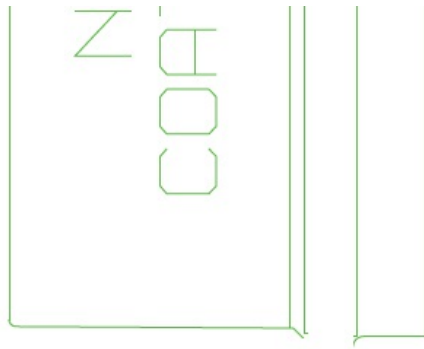
OBAGI NU-DERM® SYSTEM

NORMAL DRY

Skin Transformation Trial Kit

NO COATING





NU-DERM SYSTEM NORMAL-DRY SKIN TRANSFORMATION TRIAL

hydroquinone, homosalate, octisalate, and zinc oxide kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62032-532
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-532-07	1 in 1 CARTON	12/02/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	59 mL
Part 2	1 BOTTLE, PLASTIC	59 mL
Part 3	1 BOTTLE, PLASTIC	57 g
Part 4	1 BOTTLE, PLASTIC	28 g
Part 5	1 BOTTLE, PLASTIC	28 g
Part 6	1 TUBE	85 g

Part 1 of 6

NU-DERM TONER

cleansing (cold creams, cleansing lotions, liquids, and pads) liquid

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	

INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	DMDM HYDANTOIN (UNII: BYR0546TOW)	
INGR	IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
INGR	POTASSIUM ALUM (UNII: 1L24V9R23S)	
INGR	PANTHENOL (UNII: WW9CM0067Z)	
INGR	SAGE (UNII: 065C5D077J)	
INGR	CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
INGR	POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
INGR	ALLANTOIN (UNII: 344S277G0Z)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

color	BLUE	C48333
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		01/02/1988	

Part 2 of 6

NU-DERM GENTLE CLEANSER

cleansing (cold creams, cleansing lotions, liquids, and pads) liquid

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	

INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	BUTYLPARABEN (UNII: 3QPI1U3FV8)	
INGR	ETHYLPARABEN (UNII: 14255EXE39)	
INGR	ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
INGR	CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
INGR	SODIUM LAUROYL OAT AMINO ACIDS (UNII: FSW2K9B9N5)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	GLYCERETH-7 (UNII: 3D2Y91QZ2H)	
INGR	PANTHENOL (UNII: WW9CM0O67Z)	
INGR	DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A18X02B)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	
INGR	SAGE (UNII: 065C5D077J)	
INGR	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
INGR	APRICOT KERNEL OIL (UNII: 54JB35T06A)	
INGR	OLEYL LACTATE (UNII: B3AWW0N3GM)	

Product Characteristics

color	YELLOW	C48330
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		01/01/1988	

Part 3 of 6

NU-DERM CLEAR SKIN BLEACHING AND CORRECTOR

hydroquinone cream

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
WATER (UNII: 059QF0K00R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		57 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1988	

Part 4 of 6**NU-DERM EXFODERM SKIN SMOOTHING**

face and neck (excluding shaving preparations) lotion

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	STEARETH-20 (UNII: L0Q8IK9E08)	
INGR	CANOLA OIL (UNII: 331KBJ17RK)	
INGR	ISOHEXADECANE (UNII: 918X1OUF1E)	
INGR	MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	FYTIC ACID (UNII: 7IGF0S7R8I)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	PEG-100 STEARATE (UNII: YD01N1999R)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	PEG-150 STEARATE (UNII: 7BSG7DF10Q)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	BUTYLPARABEN (UNII: 3QPI1U3FV8)	
INGR	ETHYLPARABEN (UNII: 14255EXE39)	
INGR	ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
INGR	POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	GLYCERETH-7 (UNII: 3D2Y91QZ2H)	
INGR	DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
INGR	BIS-DIGLYCERYL POLYACYLADIPATE-2 (UNII: 6L246LAM9T)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

color WHITE C48325

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		28 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		01/01/1988	

Part 5 of 6

NU-DERM BLENDER SKIN LIGHTENER AND BLENDING

hydroquinone cream

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
TROLAMINE SALICYLATE (UNII: H8O4040BHD)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
WATER (UNII: 059QF0K00R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

Item	Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		28 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1988	

Part 6 of 6

NU-DERM SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN

homosalate, octisalate, and zinc oxide lotion

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	165 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
Hydroxyacetophenone (UNII: G1L3HT4CMH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Octyldodecyl Neopentanoate (UNII: X8725R883T)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
C15-19 Alkane (UNII: CI87N1IM01)	
Disteardimonium Hectorite (UNII: X687XDK09L)	
Polyglyceryl-2 Isostearate (UNII: 7B8OE71MQC)	
Sorbitan Olivat (UNII: MDL271E3GR)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Candelilla Wax (UNII: WL0328HX19)	
Yellow Wax (UNII: 2ZA36H0S2V)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		85 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	12/02/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		12/02/2019	

Labeler - OBAGI COSMECEUTICAL LLC (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
PURETEK CORPORATION		785961046	MANUFACTURE(62032-532) , LABEL(62032-532) , PACK(62032-532)

Establishment

Name	Address	ID/FEI	Business Operations
G.S. COSMECEUTICAL USA, INC.		017014734	MANUFACTURE(62032-532)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	MANUFACTURE(62032-532)

