

NU-DERM SYSTEM NORMAL-OILY SKIN TRANSFORMATION- 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. 3 oz. (85 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# 62032-531-00

OBAGI®
MEDICAL

OBAGI NU-DERM® SYSTEM

NORMAL OILY

Skin Transformation Kit

OBAGI[®]
MEDICAL

FRONT PANEL

OBAGI NU-DERM[®] SYSTEM

NORMAL OILY
Skin Transformation Kit

NORMAL OILY

OBAGI
MEDICAL

NORMAL OILY



The M prescription—strongly, physician-dispensed skincare system. A total systematic approach to skin care. Addresses signs of skin aging, gently exfoliates to promote cell turnover and suppresses melanocyte activity to reduce hyperpigmentation.

OBAGI NU-DERM® SYSTEM

OBAGI MEDICAL®

[illegible]

<p>Drug Form</p> <p>1. Drug Name: <u>Aspirin</u></p> <p>2. Strength: <u>325 mg</u></p> <p>3. Dosage Form: <u>Tablets</u></p> <p>4. Manufacturer: <u>Bayer</u></p> <p>5. NDC: <u>0098-01-01</u></p> <p>6. Lot Number: <u>12345678</u></p> <p>7. Expiration Date: <u>12/2025</u></p> <p>8. Quantity: <u>100 tablets</u></p> <p>9. Storage Conditions: <u>Store at room temperature, away from moisture and heat.</u></p> <p>10. Special Instructions: <u>See package insert for full prescribing information.</u></p>	
<p>Pharmacy</p> <p>1. Pharmacy Name: <u>ABC Pharmacy</u></p> <p>2. Address: <u>123 Main St, Anytown, CA 90210</u></p> <p>3. Phone: <u>(555) 123-4567</u></p> <p>4. Fax: <u>(555) 987-6543</u></p> <p>5. Email: <u>info@abcpharmacy.com</u></p> <p>6. Website: <u>www.abcpharmacy.com</u></p> <p>7. License Number: <u>123456789</u></p> <p>8. State: <u>CA</u></p> <p>9. DEA Number: <u>AA-123456789</u></p> <p>10. Pharmacist Name: <u>John Doe, Pharm.D.</u></p>	
<p>Prescription</p> <p>1. Patient Name: <u>John Doe</u></p> <p>2. Date of Birth: <u>01/01/1980</u></p> <p>3. Sex: <u>M</u></p> <p>4. Address: <u>456 Elm St, Anytown, CA 90210</u></p> <p>5. Phone: <u>(555) 987-6543</u></p> <p>6. Insurance: <u>ABC Insurance</u></p> <p>7. Refill: <u>3</u></p> <p>8. Prescribed By: <u>Dr. Jane Smith</u></p> <p>9. Date Prescribed: <u>10/26/2024</u></p> <p>10. Indication: <u>For pain relief and fever reduction.</u></p>	
<p>Notes</p> <p>1. <u>Check for allergies to aspirin or NSAIDs.</u></p> <p>2. <u>Advise patient to take with food to minimize stomach upset.</u></p> <p>3. <u>Do not take if pregnant or breastfeeding.</u></p> <p>4. <u>Do not take if you have a history of ulcers or bleeding.</u></p> <p>5. <u>Do not take if you are taking other blood thinners.</u></p> <p>6. <u>Do not take if you have kidney or liver disease.</u></p> <p>7. <u>Do not take if you have asthma.</u></p> <p>8. <u>Do not take if you have a history of heart disease.</u></p> <p>9. <u>Do not take if you have a history of high blood pressure.</u></p> <p>10. <u>Do not take if you have a history of diabetes.</u></p>	

<div data-bbox="685 75 927 298">NO COAT</div> <div data-bbox="685 298 927 1012">NORMAL <div data-bbox="790 676 823 756">OILY</div></div>	<div data-bbox="685 1012 927 1255">NO COAT</div> <div data-bbox="685 1255 927 1965">NO COATING</div>
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NU-DERM SYSTEM NORMAL-OILY SKIN TRANSFORMATION

hydroquinone, homosalate, octisalate, and zinc oxide kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62032-531
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-531-00	1 in 1 CARTON	12/02/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	57 g
Part 2	1 BOTTLE, PLASTIC	198 mL
Part 3	1 BOTTLE, PLASTIC	198 mL
Part 4	1 BOTTLE, PLASTIC	57 g
Part 5	1 BOTTLE, PLASTIC	48 g
Part 6	1 BOTTLE, PLASTIC	57 g
Part 7	1 TUBE	85 g

Part 1 of 7

OBAGI NU-DERM EXFODERM FORTE

face and neck (excluding shaving preparations), leave-on [skin care preparations (creams, lotions, powder, and sprays)] lotion

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	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
INGR	EMU OIL (UNII: 344821WD61)	
INGR	STEARIC ACID (UNII: 4ELV7Z65AP)	
INGR	STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
INGR	Glycolic Acid (UNII: 0WT12SX38S)	
COLR	WHITE ()	

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
COSMETIC		01/01/1988	

Part 2 of 7

OBAGI NU-DERM FOAMING

cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] gel

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
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	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
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	SODIUM CHLORIDE (UNII: 451W47IQ8X)	

INGR	MEDICAGO SATIVA WHOLE (UNII: DJO934BRBD)	
INGR	CHAMOMILE (UNII: FGL3685T2X)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
COLR	RED ()	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		198 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 7

OBAGI NU-DERM TONER

cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] liquid

Product Information

Route of Administration TOPICAL

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: WW9CM0O67Z)	
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)	

COLR	BLUE ()	
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		198 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 4 of 7

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: 059QF0KO0R)	
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 5 of 7

OBAGI NU-DERM HYDRATE FACIAL MOISTURIZER

face and neck (excluding shaving preparations), leave-on [skin care preparations (creams, lotions, powder, and sprays)]

Product Information	
Route of Administration	TOPICAL

Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	CAESALPINIA SPINOSA RESIN (UNII: WL3883U2PO)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	

INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	LAURETH-12 (UNII: OAH19558U1)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	STEARIC ACID (UNII: 4ELV7Z65AP)	
INGR	AVOCADO OIL (UNII: 6VNO72PFC1)	
INGR	SOY STEROL (UNII: PL360EPO9J)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	LEVOMENOL (UNII: 24WE03BX2T)	
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
INGR	TETRAHYDRODIFERULOYLMETHANE (UNII: 00U0645U03)	
INGR	PANTHENOL (UNII: W9CM0O67Z)	
INGR	MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
INGR	SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
INGR	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
INGR	ALLANTOIN (UNII: 344S277G0Z)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
COLR	WHITE ()	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		48 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		11/07/2012	

Part 6 of 7

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: 059QF0KO0R)	
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 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 7 of 7

NU-DERM SUN SHIELD MATTE BROAD SPECTRUM SPF 50
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 DRUG	M020	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(62032-531) , LABEL(62032-531) , PACK(62032-531)

Establishment			
Name	Address	ID/FEI	Business Operations
G.S. COSMECEUTICAL USA, INC.		017014734	MANUFACTURE(62032-531)

Establishment			
Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	MANUFACTURE(62032-531)