

**NU-DERM TRAVEL SET NORMAL/DRY SKIN TRANSFORMATION SYSTEM-  
hydroquinone, octinoxate and zinc oxide**

**Obagi Cosmeceuticals 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](#).*

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

**Obagi Nu-Derm Blender<sup>®</sup>**  
**(Hydroquinone USP, 4%)**  
**Skin Bleaching Cream**

**Obagi Nu-Derm Sunfader<sup>®</sup>**  
**(Hydroquinone USP, 4%,**  
**Octinoxate USP, 7.5%**  
**and Oxybenzone USP, 5.5%)**  
**Skin Bleaching Cream with Sunscreens**

**Rx Only**

FOR EXTERNAL USE ONLY

**DESCRIPTION**

Hydroquinone is 1,4-benzenediol. Hydroquinone occurs as fine, white needles. 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 110.0.



Each gram of **Obagi Nu-Derm Blender** contains Hydroquinone USP 40 mg/gm in a base of purified water, glycerin, cetyl alcohol, PPG-2 myristyl ether propionate, sodium lauryl sulfate, TEA-salicylate, lactic acid, phenyl trimethicone, tocopheryl acetate, sodium metabisulfite, ascorbic acid, methylparaben, saponins, disodium EDTA, BHT, and propylparaben.

Each gram of **Obagi Nu-Derm Clear** contains Hydroquinone USP 40 mg/gm in a base of purified water, cetyl alcohol, glycerin, sodium lauryl sulfate, stearyl alcohol, tocopheryl acetate, ascorbic acid, sodium metabisulfite, lactic acid, saponins, disodium EDTA, methylparaben, BHT, propylparaben, and butylparaben.

Each gram of **Obagi Nu-Derm Sunfader** contains Hydroquinone USP 40 mg/gm, Octinoxate USP, 7.5%, and Oxybenzone USP, 5.5%, in a base of purified water, cetyl alcohol, glycerin, sodium lauryl sulfate, stearyl alcohol, tocopheryl acetate, ascorbic acid, sodium metabisulfite, disodium EDTA,

methylparaben, saponins, propylparaben, BHT, and butylparaben.

## **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 sunblocking agents or sunscreen agents contained in Obagi Nu-Derm Sunfader.

## **INDICATIONS AND USAGE**

The gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentigines, and other unwanted areas of melanin hyperpigmentation. Obagi Nu-Derm Sunfader is intended for daytime use as it contains sunscreen agents.

## **CONTRAINDICATIONS**

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

## **WARNINGS**

### **Caution**

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 medication.

Test for skin sensitivity before using by applying a small amount to an unbroken patch of skin and check in 24 hours. Minor redness is not a contraindication, but where there is itching or vesicle formation or excessive inflammatory response, further treatment is not advised. Close patient supervision is recommended.

Avoid contact with eyes. In case of accidental contact, patient should rinse eyes thoroughly with water and contact physician. A bitter taste and anesthetic effect may occur if applied to lips.

Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight exposure sustains melanocytic activity. Obagi Sunfader is formulated for use as a skin bleaching agent and should not be used for the prevention of sunburn.

### **Warning**

Contains sodium metabisulfite, a sulfite that may cause serious allergic type reactions (e.g., hives, itching, wheezing, anaphylaxis, severe asthma attacks) in certain susceptible persons.

## **PRECAUTIONS**

### **(SEE WARNINGS)**

### **General**

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 medication should be discontinued and the physician notified immediately.

## **DOSAGE AND ADMINISTRATION**

A thin application should be applied to the affected area 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, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent repigmentation.

## **HOW SUPPLIED**

Obagi Nu-Derm Blender is available as follows:

2 oz. (57 gm) bottle	NDC 62032-100-36
1 oz. (28.5 gm) bottle	NDC 62032-100-10

Obagi Nu-Derm Clear is available as follows:

2 oz. (57 gm) bottle	NDC 62032-101-36
1 oz. (28.5 gm) bottle	NDC 62032-101-10

Obagi Nu-Derm Sunfader is available as:

2 oz. (57 gm) bottle	NDC 62032-116-36
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Store at 25°C (77°F); excursion permitted to 15°C-30°C (59°F-86°F).

OMP, Inc.  
Long Beach, CA 90802  
USA  
1-800-636-7546

Rev. 8/03

**PRINCIPAL DISPLAY PANEL - Kit Carton**

**OBAGI®  
SYSTEM**

**NU - DERM®**

**skin transformation system**

**travel set**

normal/dry

NU-DERM  
SYSTEM  
OBAGI

skin transformation system

OBAGI®  
SYSTEM  
NU-DERM®

skin transformation system

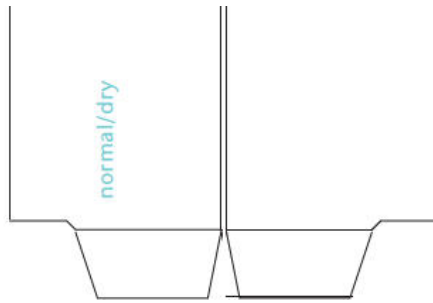
travel set  
normal/dry

This Obagi Nu-Derm® Skin Transformation System Includes:

travel set

skin transformation system





## NU-DERM TRAVEL SET NORMAL/DRY SKIN TRANSFORMATION SYSTEM

hydroquinone, octinoxate and zinc oxide kit

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:62032-500
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-500-60	1 in 1 CARTON	12/02/2004	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	28 g
Part 2	1 BOTTLE, PLASTIC	57 g
Part 3	1 BOTTLE, PLASTIC	30 mL
Part 4	1 BOTTLE, PLASTIC	60 mL
Part 5	1 BOTTLE, PLASTIC	60 mL
Part 6	1 BOTTLE, PLASTIC	28.5 g

### Part 1 of 6

## NU-DERM BLENDER SKIN LIGHTENER AND BLENDING

hydroquinone cream

### Product Information

<b>Route of Administration</b>	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)	
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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (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		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 2 of 6

### NU-DERM CLEAR SKIN BLEACHING AND CORRECTOR

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)	
BUTYLPARABEN (UNII: 3QP11U3FV8)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
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 3 of 6

### NU-DERM HEALTHY SKIN PROTECTION SPF 35

octinoxate and zinc oxide cream

### Product Information

Route of Administration	TOPICAL
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**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	90 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
WATER (UNII: 059QF0K00R)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
METHYLPARABEN (UNII: A2I8C7H9T)	
LAURETH-7 (UNII: Z95S6G8201)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLPARABEN (UNII: 3QPIU3FV8)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

**Product Characteristics**

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 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
OTC monograph final	part352	01/01/2002	

## Part 4 of 6

### NU-DERM GENTLE CLEANSER

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

#### Product Information

Route of Administration TOPICAL

#### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	METHYLPARABEN (UNII: A2I8C7H9T)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	BUTYLPARABEN (UNII: 3QPIU3FV8)	
INGR	ETHYLPARABEN (UNII: 14255EXE39)	
INGR	ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
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: WV9CM0O67Z)	
INGR	DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	
INGR	SAGE (UNII: 065C5D077J)	
INGR	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
INGR	APRICOT KERNEL OIL (UNII: 54JB35T06A)	
INGR	CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	

#### Product Characteristics

Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		60 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 5 of 6

### NU-DERM TONER

face and neck (excluding shaving preparations) 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	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	DMDM HYDANTOIN (UNII: BYR0546TOW)	
INGR	IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
INGR	POTASSIUM ALUM (UNII: 1L24V9R23S)	
INGR	PANTHENOL (UNII: WV9CM0O67Z)	
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)	
INGR	HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	

## Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		60 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 6 of 6

### NU-DERM EXFODERM

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)	

## Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	

<b>Contains</b>	
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<b>Packaging</b>				
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		28.5 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/01/1988	

<b>Marketing Information</b>			
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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		12/02/2004	

**Labeler** - Obagi Cosmeceuticals LLC (790553353)

<b>Establishment</b>			
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Name	Address	ID/FEI	Business Operations
PURETEK CORPORATION		785961046	MANUFACTURE(62032-500) , LABEL(62032-500) , PACK(62032-500)

<b>Establishment</b>			
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Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	MANUFACTURE(62032-500)

<b>Establishment</b>			
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Name	Address	ID/FEI	Business Operations
Bay Cities Container Corporation		066229618	RELABEL(62032-500) , REPACK(62032-500)