NU-DERM CLEAR SKIN BLEACHING AND CORRECTOR- hydroquinone cream
NU-DERM BLENDER SKIN LIGHTENER AND BLENDING- hydroquinone cream
NU-DERM SUNFADER SKIN LIGHTENER WITH SUNSCREEN (SPF 15) PABA FREE- hydroquinone, octinoxate, and oxybenzone lotion
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.

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

Rx Only

For external use only

DESCRIPTION

Hydroquinone is 1, 4-benzenediol. The drug is freely soluble in water and in alcohol. Chemically, hydroquinone is designed 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 ingredient: Hydroquinone USP, 4% (40 mg/g)

Inactive ingredients: water, cetyl alcohol, glycerin, sodium lauryl sulfate, stearyl alcohol, lactic acid, tocopheryl acetate, ascorbic acid, sodium metabisulfite, disodium EDTA, methylparaben, BHT, propylparaben, saponins, butylparaben

Each gram of Obagi Nu-Derm Blender contains:

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

Inactive ingredients: 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, disodium EDTA, propylparaben, saponins, BHT

Each gram of Obagi Nu-Derm Sunfader contains:

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

Inactive ingredients: water, cetyl alcohol, glycerin, sodium lauryl sulfate, stearyl alcohol, tocopheryl acetate, ascorbic acid, sodium metabisulfite, disodium EDTA, methylparaben, BHT, saponins, propylparaben, 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 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. Minor redness is not a contraindication, but where there is itching or vesicle formation or excessive inflammatory response, product should be discontinued and physician consulted. 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.

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, a sunblocking 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°C-25°C (59°F-77°F). Keep out of direct sunlight.

1-800-636-7546

Manufactured for:
Obagi Cosmeceuticals LLC,
Long Beach, CA 90806

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www.obagi.com

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PRINCIPAL DISPLAY PANEL - 57 g Bottle Label - 3

OBAGI

NU-DERM®
NDC 62032-101-36

AM CLEAR
PM
3

SKIN BLEACHING
& CORRECTOR CREAM

HYDROQUINONE USP, 4%
Rx ONLY

Net wt. 2 oz. (57g)

PRINCIPAL DISPLAY PANEL - 57 g Bottle Label - 5

OBAGI

NU-DERM®
NDC 62032-100-36

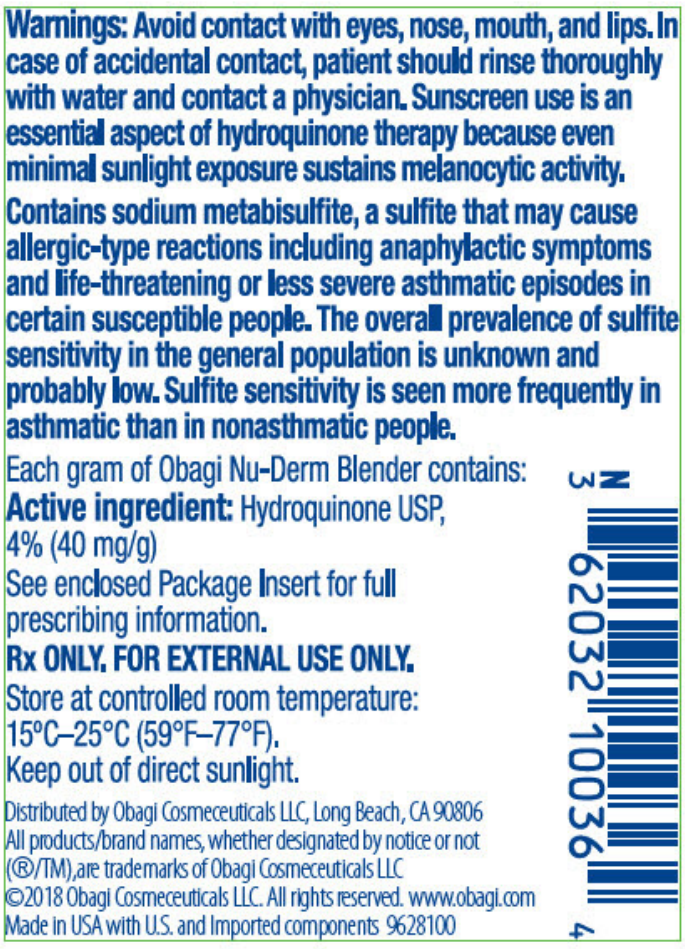
BLENDER®

PM
5

SKIN LIGHTENER
& BLENDING CREAM

HYDROQUINONE USP, 4%
Rx ONLY

Net wt. 2 oz. (57g)



PRINCIPAL DISPLAY PANEL - 57 g Bottle Label - 6

OBAGI

NU-DERM®
NDC 62032-116-36

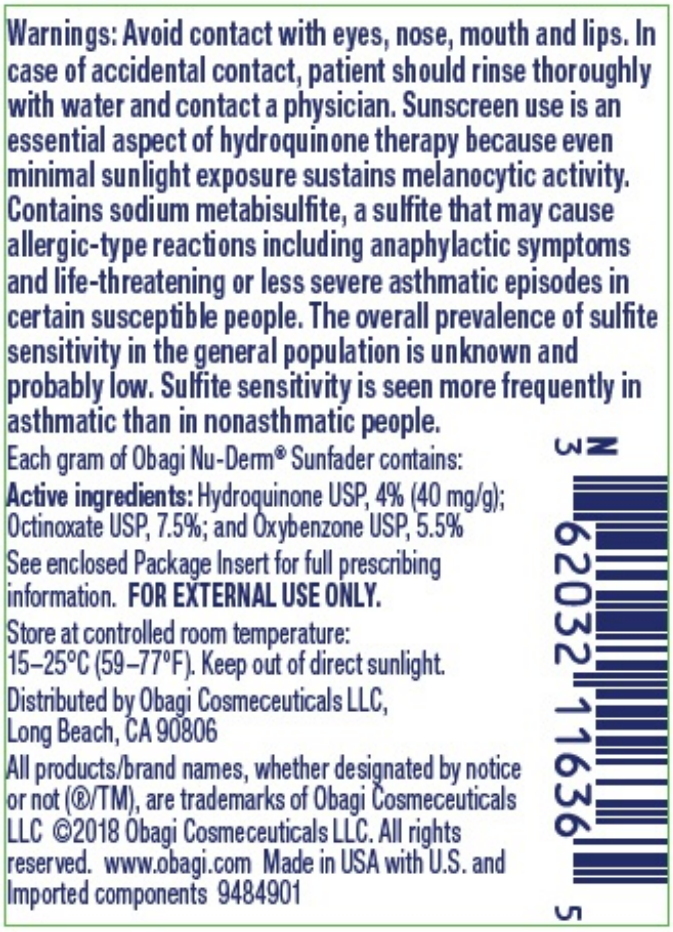
AM
6

SUNFADER®
HYDROQUINONE USP, 4%

SKIN LIGHTENER
WITH SUNSCREEN
(SPF 15) PABA-FREE

Rx only

Net wt. 2 oz. (57 g)



NU-DERM CLEAR SKIN BLEACHING AND CORRECTOR

hydroquinone cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62032-101
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**
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:62032-101-36	57 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1988	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		01/01/1988	

NU-DERM BLENDER SKIN LIGHTENER AND BLENDING

hydroquinone cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62032-100
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**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TROLAMINE SALICYLATE (UNII: H8O4040BHD)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
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	NDC:62032-100-10	28 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1988	
2	NDC:62032-100-36	57 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1988	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		01/01/1988	

NU-DERM SUNFADER SKIN LIGHTENER WITH SUNSCREEN (SPF 15) PABA FREE

hydroquinone, octinoxate, and oxybenzone lotion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62032-116
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
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	55 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-116-36	57 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1984	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		01/01/1984	

Labeler - Obagi Cosmeceuticals LLC (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	MANUFACTURE(62032-101, 62032-100, 62032-116) , LABEL(62032-101, 62032-100, 62032-116) , PACK(62032-101, 62032-100, 62032-116)

Establishment

Name	Address	ID/FEI	Business Operations
G.S. COSMECEUTICAL USA, INC.		017014734	MANUFACTURE(62032-101, 62032-100)

Revised: 11/2019 Obagi Cosmeceuticals LLC