CONDITION AND ENHANCE CLEAR SKIN BLEACHING AND CORRECTOR- hydroquinone cream
CONDITION AND ENHANCE BLENDER SKIN LIGHTENER AND BLENDING- hydroquinone cream
OMP, INC.

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® Condition & Enhance Clear
(Hydroquinone USP, 4%)
Skin Bleaching Cream

Obagi® Condition & Enhance Blender®
(Hydroquinone USP, 4%)
Skin Bleaching Cream

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 $C_6 H_6 O_2$; molecular weight is 110.0.

Obagi® Condition & Enhance 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.

$C_6H_6O_2$

Obagi® Condition & Enhance 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.

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 Condition & Enhance.

INDICATIONS AND USAGE

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

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.

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 Condition and Enhance Blender is available as follows:

2 oz. (57 gm) bottle	NDC 62032-115-36
1 oz. (28.5 gm) bottle	NDC 62032-115-10

Obagi Condition and Enhance Clear is available as follows:

2 oz. (57 gm) bottle	NDC 62032-117-36

Store at 25°C (77°F); excursion permitted to 15°C-30°C (59°F-86°F).

OBAGI®
MEDICAL

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

80707910U Rev. 6/07

PRINCIPAL DISPLAY PANEL - 57 g Bottle Label

OBAGI®
MEDICAL

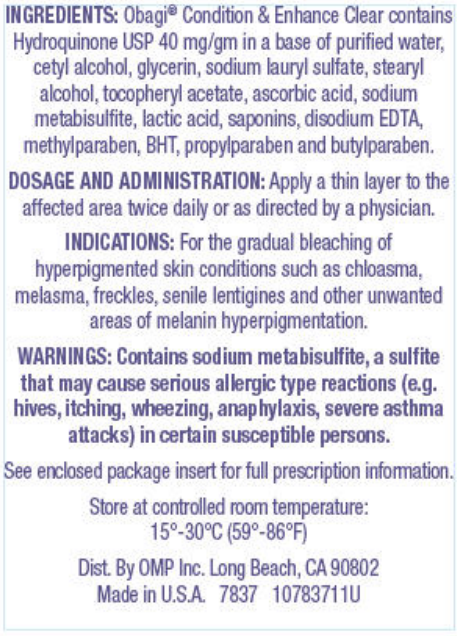
CONDITION & ENHANCE

NDC 62032-117-36
AM • PM
3

clear

Skin Bleaching & Corrector Cream
Hydroquinone USP, 4%
Rx Only

NET WT. 2 OZ. (57 g)



PRINCIPAL DISPLAY PANEL - 57 g Bottle Label

OBAGI®
MEDICAL

CONDITION & ENHANCE

NDC 62032-115-36
PM
5

blender®

Skin Lightener & Blending Cream
Hydroquinone USP, 4%
Rx Only

NET WT. 2 OZ. (57 g)

INGREDIENTS: Obagi® Condition & Enhance 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.

DOSAGE AND ADMINISTRATION: Apply a thin layer to the affected area twice daily or as directed by a physician.

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

WARNINGS: 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.

See enclosed package insert for full prescription information.

Store at controlled room temperature: 15°-30°C (59°-86°F)

Dist. by OMP Inc. Long Beach, CA 90802
Made in U.S.A. 7772 10777211U

CONDITION AND ENHANCE CLEAR SKIN BLEACHING AND CORRECTOR

hydroquinone cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62032-117
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: 3QPI1U3FV8)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (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	NDC:62032-117-36	57 g in 1 BOTTLE, PLASTIC		

Marketing Information

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

CONDITION AND ENHANCE BLENDER SKIN LIGHTENER AND BLENDING

hydroquinone cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62032-115
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)	
TROLAMINE SALICYLATE (UNII: H8O4040BHD)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (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	NDC:62032-115-10	28.5 g in 1 BOTTLE, PLASTIC		
2	NDC:62032-115-36	57 g in 1 BOTTLE, PLASTIC		

Marketing Information

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

Labeler - OMP, INC. (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
PURETEK CORPORATION		785961046	MANUFACTURE(62032-117, 62032-115) , LABEL(62032-117, 62032-115) , PACK(62032-117, 62032-115)

Establishment

Name	Address	ID/FEI	Business Operations
Ei INC.		105803274	MANUFACTURE(62032-117, 62032-115) , LABEL(62032-117, 62032-115) , PACK(62032-117, 62032-115) , ANALYSIS(62032-117, 62032-115)

Revised: 12/2011 OMP, INC.