

**CONDITION AND ENHANCE SYSTEM FULL-SIZE NON-SURGICAL- hydroquinone,
octinoxate and zinc oxide
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

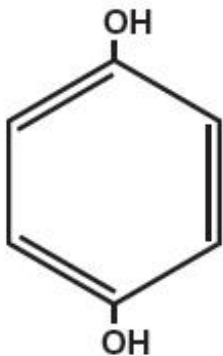
Rx Only

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 C₆H₆O₂; 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.



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 lentiginos, 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 - Kit Carton

OBAGI® MEDICAL

OBAGI®

CONDITION & ENHANCE SYSTEM

For Use with Nonsurgical Procedures

This Obagi® Condition & Enhance System includes:

Foaming Gel

6.7 FL. OZ. (200 mL)

Toner

6.7 FL. OZ. (200 mL)

Clear (2)

NET WT. 2 OZ. (57 g)

Hydroquinone USP, 4%

Rx Only

Exforderm[®] Forte

NET WT. 2 OZ. (57 g)

Blender[®]

NET WT. OZ. (57 g)

Hydroquinone USP, 4%

Rx Only

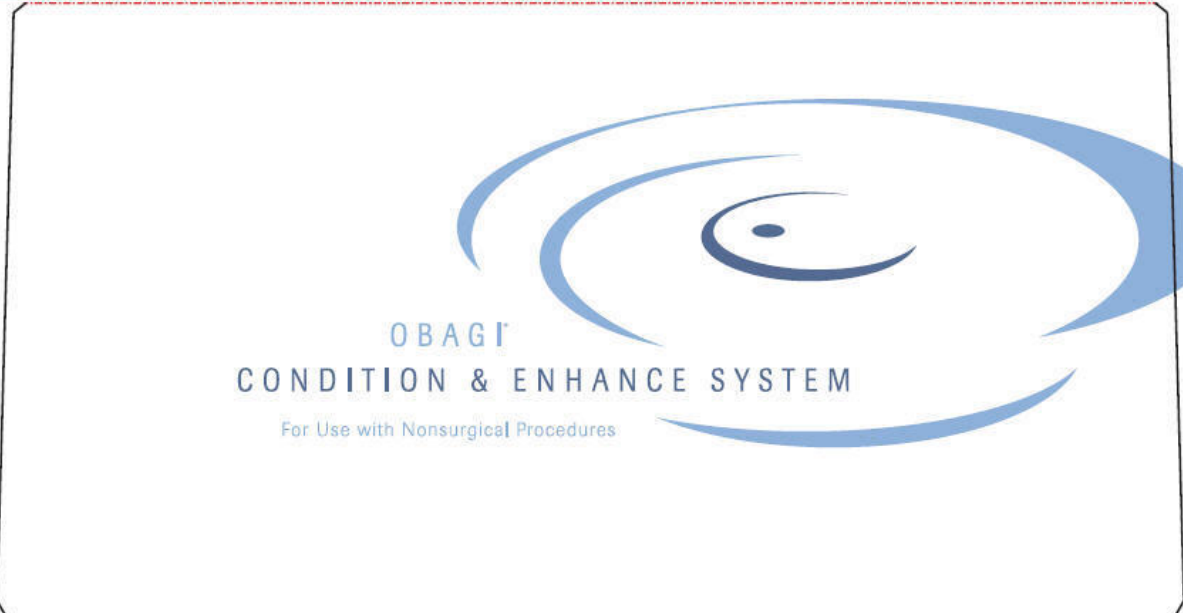
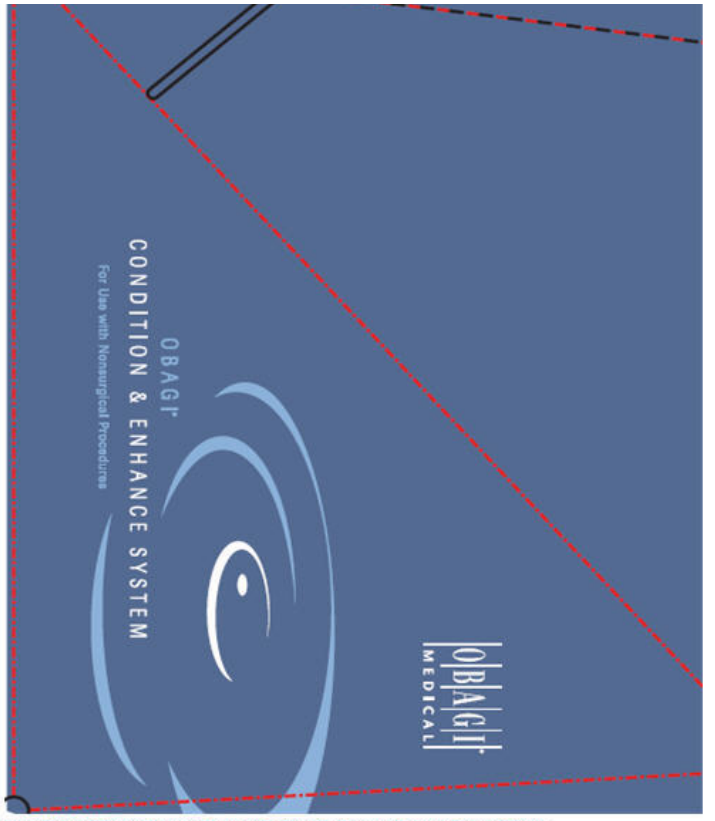
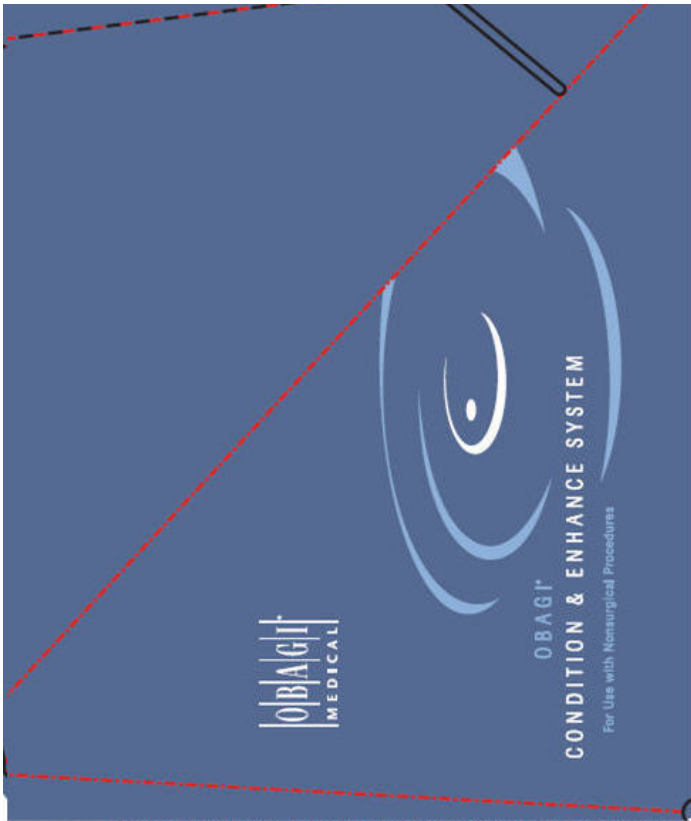
Healthy Skin

Protection

SPF 35

3 FL. OZ. (90 mL)

Patient Instructions



OBAGI[®]
CONDITION & ENHANCE SYSTEM
 For Use with Nonsurgical Procedures



What to Expect

The desire for healthy, youthful and attractive skin is why you are undergoing facial aesthetic procedures. The Obagi[®] Condition & Enhance System uses proven ingredients and penetrating technologies to help ensure a successful outcome. This system has been shown to improve the overall results of facial aesthetic procedures.

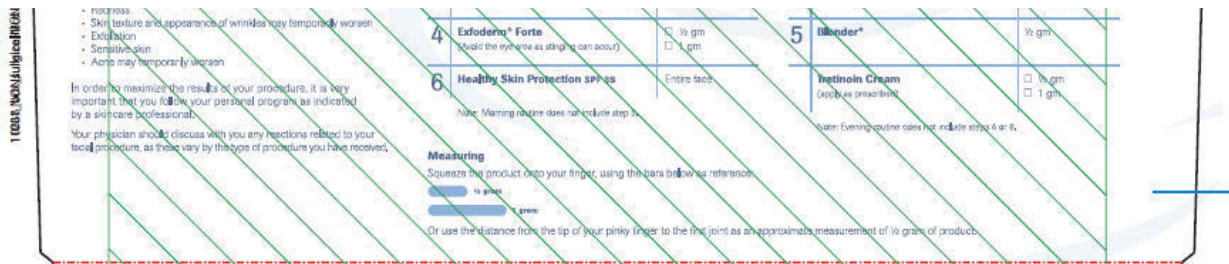
The length of time that it takes to condition your skin varies. You should begin to notice visible improvements to your skin within a 6-week period.

It is important to understand that you will experience some reactions during your skin conditioning process. These reactions are normal and part of the transformation process. You may experience one or more of these symptoms:

- Dryness

Daily Product Routines

Morning		Evening	
PRODUCT	QUANTITY	PRODUCT	QUANTITY
1 Foaming Gel	Entire face	1 Foaming Gel	Entire face
2 Toner	Apply liberally with cotton pad to the entire face	2 Toner	Apply liberally into cotton pad to the entire face
3 Clear	<input type="checkbox"/> 1/2 gm <input type="checkbox"/> 1 gm	3 Clear	<input type="checkbox"/> 1/2 gm <input type="checkbox"/> 1 gm



CONDITION AND ENHANCE SYSTEM FULL-SIZE NON-SURGICAL

hydroquinone, octinoxate and zinc oxide kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62032-509
---------------------	-------------------------	---------------------------	---------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-509-01	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	57 g
Part 2	2 BOTTLE, PLASTIC	114 g
Part 3	1 BOTTLE, PLASTIC	90 mL
Part 4	1 BOTTLE, PLASTIC	200 mL
Part 5	1 BOTTLE, PLASTIC	200 mL
Part 6	1 BOTTLE, PLASTIC	57 g

Part 1 of 6

CONDITION AND ENHANCE BLENDER SKIN LIGHTENER AND BLENDING

hydroquinone cream

Product Information

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)	
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 (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	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	

Part 2 of 6

CONDITION AND ENHANCE CLEAR SKIN BLEACHING AND CORRECTOR
hydroquinone cream

Product Information

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)	
BUTYL PARABEN (UNII: 3QPI1U3FV8)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (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	

Part 3 of 6**CONDITION AND ENHANCE HEALTHY SKIN PROTECTION SPF 35**

octinoxate and zinc oxide cream

Product Information

Item Code (Source)	NDC:62032-119
Route of Administration	TOPICAL

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: 059QF0KO0R)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
LAURETH-7 (UNII: Z95S6G8201)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
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	NDC:62032-119-90	90 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph final	part352	01/01/2002	

Part 4 of 6

CONDITION AND ENHANCE FOAMING

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

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: 3QPII1U3FV8)	
INGR	ETHYLPARABEN (UNII: 14255EXE39)	
INGR	ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
INGR	SODIUM LAUROYL OAT AMINO ACIDS (UNII: FSW2K9B9N5)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O1IKX)	
INGR	SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	ALFALFA WHOLE (UNII: DJO934BRBD)	
INGR	CHAMOMILE (UNII: FGL3685T2X)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
INGR	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		200 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
--------------------	--	----------------------	--------------------

Cosmetic		01/01/1988	
----------	--	------------	--

Part 5 of 6

CONDITION AND ENHANCE TONER

face and neck (excluding shaving preparations) liquid

Product Information

Route of Administration	TOPICAL
-------------------------	---------

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 BUTYL CARBAMATE (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		200 mL in 1 BOTTLE, PLASTIC		

Marketing Information

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

Part 6 of 6

CONDITION AND ENHANCE EXFODERM FORTE

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: 2DMT128MIS)	
INGR	GLYCOLIC ACID (UNII: 0WT12SX38S)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	LACTIC ACID (UNII: 33X04XA5AT)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	EMU OIL (UNII: 344821WD61)	
INGR	STEARIC ACID (UNII: 4ELV7Z65AP)	
INGR	STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	

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		

Marketing Information

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		08/20/2007	

Labeler - OMP, INC. (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
PURETEK CORPORATION		785961046	MANUFACTURE(62032-509) , LABEL(62032-509) , PACK(62032-509)

Establishment

Name	Address	ID/FEI	Business Operations
Ei INC.		105803274	MANUFACTURE(62032-509) , LABEL(62032-509) , PACK(62032-509) , ANALYSIS(62032-509)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American Products		611921669	MANUFACTURE(62032-509)

Establishment

Name	Address	ID/FEI	Business Operations
Bay Cities Container Corporation		066229618	RELABEL(62032-509) , REPACK(62032-509)

Revised: 5/2012

OMP, INC.