ELASTIDERM DECOLLETAGE SKIN LIGHTENING COMPLEX CHEST AND NECK-
hydroquinone lotion
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® Skin Lightening Complex
(Hydroquinone USP, 4%)
Skin Bleaching Cream

Rx Only
FOR EXTERNAL USE ONLY

Each gram of Skin Lightening Complex 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

Description:

Hydroquinone 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 $C_6H_6O_2$; the molecular weight is 110.11 g/mol. The chemical structure is in the diagram to the right.

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.

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.

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.

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 medication.

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, the product should be discontinued and a physician consulted. Close patient supervision is recommended.

Avoid contact with the eyes, nose, mouth, and lips. In case of accidental contact, the 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.

How Supplied:

Obagi Skin Lightening Complex is available as follows:

2.0 oz. (57 g) tube
NDC 62032-120-60

Store at controlled room temperature:
15°C-25°C (59°F-77°F)

OBAGI®
MEDICAL

Long Beach, CA 90806
Made in USA. www.obagi.com
60650612Z 09/12

PRINCIPAL DISPLAY PANEL - 57 g Carton

NDC 62032-120-60

OBAGI®
MEDICAL

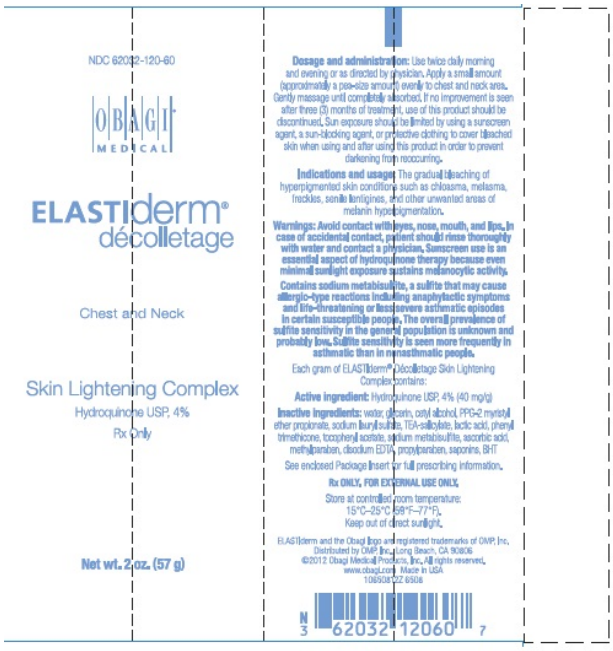
ELASTIderm®
décolletage

Chest and Neck

Skin Lightening Complex

Hydroquinone USP, 4%
Rx Only

Net wt. 2 oz. (57 g)



ELASTIDERM DECOLLETAGE SKIN LIGHTENING COMPLEX CHEST AND NECK

hydroquinone lotion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62032-120
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 (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	GRAY	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-120-60	1 in 1 CARTON		
1		57 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		12/01/2010	

Labeler - OMP, INC. (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	MANUFACTURE(62032-120) , LABEL(62032-120) , PACK(62032-120)

Revised: 6/2014 OMP, INC.