SKIN LIGHTENER- hydroquinone cream
Axia Medical Solutions, 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.

Dermesse Skin Lightener

RX Only

FOR EXTERNAL USE ONLY

DERMESSE SKIN LIGHTENER contains: Hydroquinone 40mg/gm. See label on bottle for complete list of ingredients. Following is its chemical structure:

CLINICAL PHARMACOLOGY

Topical application of hydroquinone produces a reversible depigmentation of the skin by inhibition of the enzymatic hydroquinone. oxidation of tyrosine to 3, 4-dihydroxyphenylalanine (dopa) and suppression of other melanocyte metabolic processes.

The selective inhibition of the enzyme affects melanogenesis in the melanocytes resulting in cessation of melanin formation and subsequent reduction in pigmentation. Additional studies indicate Hydroquinone acts on the essential subcellular metabolic processes of melanocytes with resultant cytolysis, i.e. nonenzymediated depigmentation.

Exposure to sunlight or ultraviolet light will cause regimentation of the bleached areas, which may be prevented by the use of sunblocking agents.

INDICATIONS AND USAGE

DERMESSE SKIN LIGHTENER is indicated for the gradual bleaching of hyperpigmented skin conditions such as chlosma, 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

A. **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.

B. Test for skin sensitivity before using Hydroquinone Cream 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 and vesicle formation or excessive inflammatory response, further treatment is not advised. Close patient supervision is recommended. Contact with the eyes should be avoided. 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. Keep out of reach of children. If no bleaching or lightening effect is noted after 2 months of treatment use, Hydroquinone Cream should be discontinued. This product is formulated for use as a skin bleaching agent and should not be used for the prevention of sunburn.
C. Sunscreen use is an essential aspect of Hydroquinone therapy because even minimal sunlight sustains melanocytic activity. After clearing and during maintenance therapy, sun exposure should be avoided on bleached skin by application of a sunscreen or sunblock agent, or protective clothing to prevent repigmentation. There are no sunblocking or sunscreening agents in DERMESSE SKIN LIGHTENER and since minimal sunlight exposure may reverse the bleaching effect of this preparation. It should be used only at night or on areas of the body covered by protective clothing. During the daytime, sunblocking or broad spectrum sunscreen preparations or protective clothing should be used to prevent the bleached areas from repigmentation.
D. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
E. Warning: Contains sodium metabisulfite, a sulfite that may cause serious allergic type reactions (e.g., hives, itching, wheezing, anaphylaxis, severe asthma attack) in certain susceptible persons.

PRECAUTIONS

See Warnings

A. 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 can affect reproductive capacity. It is not known to what degree, if any, topical Hydroquinone is absorbed systemically. Topical Hydroquinone should be used in women only when clearly indicated.

B. 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.

C. Pediatric usage

Safety and effectiveness in children below the age of 12 years have not been established.

ADVERSE REACTIONS

No systemic reactions have been reported. Occasional cutaneous hypersensitivity (localized contact dermatitis) may occur in which case the medication should be discontinued and the physician notified immediately

OVERDOSAGE

There have been no systemic reactions reported from the use of topical Hydroquinone. However, 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.

DRUG DOSAGE AND ADMINSTRATION

A thin application of DERMESSE SKIN LIGHTENER should be applied to the affected area twice daily or as directed by a physician. Consult product label for instructions on whether to rub in or not. There is no recommendation for children under the age of 12 years of age except under the advice and supervision of a physician.

HOW SUPPLIED

DERMESSE SKIN LIGHTENER is available as follows:

2 Oz. (57g) bottle

DERMESSE SKIN LIGHTENER should be stored at controlled room temperature (15°-30°C) (59°-86°F). Darkening of this product is normal. This will not affect performance or safety.

Distributed By

Axia Medical Solutions Carlsbad, California 92011

DERMESSE™

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SKIN LIGHTENER Rx

Indicated for the depigmentation of dark areas of the skin such as age spots, liver spots, freckles, and other unwanted areas of melanin hyperpigmentation.

2 fl.oz. (57mL)

DIRECTIONS: Apply a thin layer to affected areas as needed, or as directed by a physician. If no improvement is seen after 2 to 3 months of treatment, use of this product should be discontinued. Lightening effect of this product may not be noticeable when used on very dark skin. Sun exposure should be limited by using a sunscreen, a sun block, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from recurring.

WARNINGS: KEEP OUT OF REACH OF CHILDREN. 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. For external use only. Avoid contact with the eyes. Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a physician. DO NOT use on children under 12 years of age unless directed by a physician. If swallowed, get medical help or contact a Poison Control Center right away.

Storage: Store at controlled room temperature 15-30°C (59-86°F), away from direct sunlight.

Active Ingredient: Hydroquinone 4%

Other Ingredients: Ascorbic Acid, Butylated Hydroxytoluene, Cetyl Alcohol, Edetate Disodium, Glycerin, Glycolic Acid, Methylparaben, Propylparaben, Purified Water, Saponins, Sodium Lauryl Sulfate, Sodium Metabisulfite, Stearyl Alcohol, Tocopheryl Acetate (Vitamin E).

DERMESSE™

Distributed by Axia Medical Solutions
Carlsbad, California 92011

DERMESSE SKIN LIGHTENER

(Hydroquinone USP, 4%)
Skin Bleaching Cream

Rx Only.

For external use only.

Description

DERMESSE SKIN LIGHTENER contains: Hydroquinone 40 mg/gm. See label on bottle for complete list of ingredients.

Following is its chemical structure:

CLINICAL PHARMACOLOGY

Topical application of Hydroquinone produces a reversible depigmentation of the skin by inhibition of the enzymatic oxidization of tyrosine to 3,4-dihydroxyphenylalanine (dopa) and suppression of other melanocyte metabolic processes.

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Exposure to sunlight or ultraviolet light will cause repigmentation of the bleached areas, which may be prevented by the use of sunblocking agents.

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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.

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A. 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.

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There are no sunblocking or sunscreening agents in **DERMESSE SKIN LIGHTENER** and since minimal sunlight exposure may reverse the bleaching effect of this preparation. It should be used only at night or on areas of the body covered by protective clothing. During the daytime, sunblocking or broad spectrum suncreen preparations or protective clothing should be used to prevent the bleached areas from repigmentation.

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B. 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.

C. Pediatric Usage. Safety and effectiveness in children below the age of 12 years have not been established.

ADVERSE REACTIONS

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OVERDOSAGE

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DRUG DOSAGE AND ADMINISTRATION

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HOW SUPPLIED

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2 Oz. (57g) bottle

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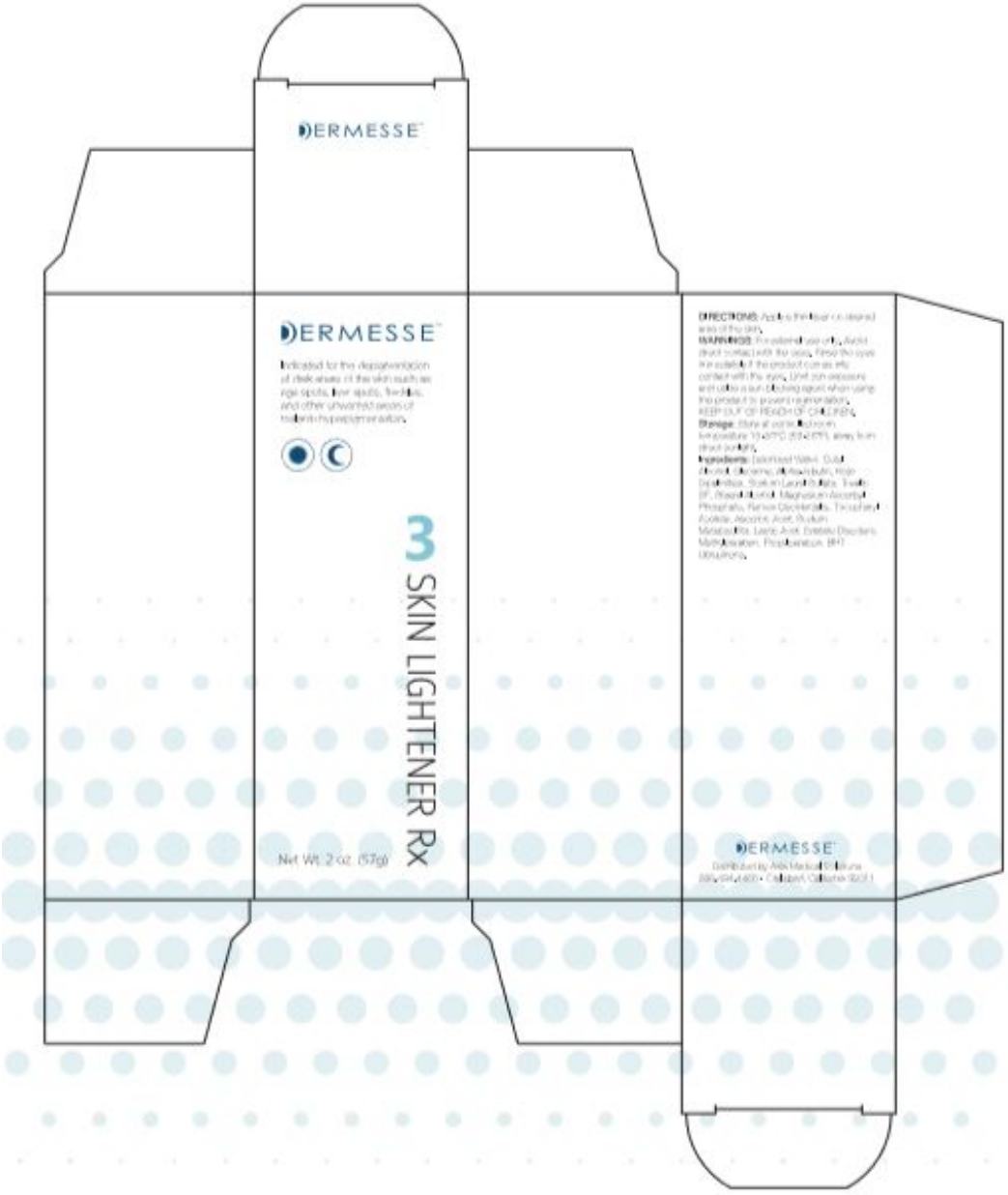

SKIN LIGHTENER

hydroquinone cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68723-142
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
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
CAULOSIDE D (UNII: 4N5Z068GAZ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
.ALPHA.-TOCOPHEROL SUCCINATE, D- (UNII: LU4B53JYVE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68723-142-02	1 in 1 BOX	12/01/1990	
1		57 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		12/01/1990	

Labeler - Axia Medical Solutions, LLC (929224694)

Establishment

Name	Address	ID/FEI	Business Operations
Axia Medical Solutions, LLC		929224694	manufacture(68723-142)

Revised: 2/2021 Axia Medical Solutions, LLC