

PURE VALLEY MIRACLE AGE SPOT- hydroquinone lotion
Concept Laboratories, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Pure Valley® Miracle Age Spot

Drug Facts

Active ingredient

Hydroquinone 1.5%

Purpose

Skin Lightener

Uses

for the gradual fading of dark (brownish) discolorations in the skin such as

- freckles
- age and liver spots
- pigment in the skin that may occur in pregnancy or from the use of oral contraceptives

Warnings

For external use only.

- avoid contact with eyes. If eye contact occurs flush thoroughly with water.
- some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor
- **do not use** on children under 12 years of age unless directed by a doctor
- **if pregnant or nursing**, seek the advice of a health professional before using

When using this product do not use on cracked, irritated or inflamed skin

Keep out of reach of children.

- if swallowed, get medical help or contact a Poison Control Center right away

Directions

- Adults: apply a small amount as a thin layer on the affected area twice daily, or use as directed by a doctor. If no improvement is seen after 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.
- for sensitive skin, test product on a small section of your skin inside your elbow

Inactive ingredients

Water (Aqua), Glyceryl Stearate SE, Cetearyl Alcohol, Mineral Oil, Cetareth-20, Isopropyl Myristate, Glycerin, Petrolatum, Butyrospermum Parkii (Shea Butter), Sodium Metabisulfite, Propylene Glycol, DMDM Hydantoin, Methylparaben, Propylparaben, Citric Acid, Glycolic Acid, Ascorbic Acid,

Glycyrrhiza Glabra (Licorice) Root Extract, Disodium EDTA, Fragrance.

Other Information

- For sensitive skin, test product on a small section of your skin inside your elbow. If no irritation develops after 24 hours proceed with application.
- Close product lid tightly after each use. Cream may darken when exposed to air. Product performance will not be affected.
- Do not use this product in combination with externally applied products containing resorcinol, phenol, salicylic acid or any type of acne product unless directed by a doctor.
- 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 darkening from reoccurring.

Questions or comments?

Call 1-888-373-8831 or visit www.conceptlabs.org

Manufactured by Concept Laboratories, Inc., Chicago, IL 60642 (USA)

PRINCIPAL DISPLAY PANEL - 113 g Jar Label

PURE VALLEY®

Miracle-Age Spot

FADE CREME

Skin Lightening

with Alpha Hydroxy Acids & Shea Butter

4oz. (113g)e

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Drug Facts (continued)

Directions ■ Adults: apply a small amount as a thin layer on the affected area twice daily, or use as directed by a doctor ■ for sensitive skin, test product on a small section of your skin inside your elbow

Other information

Read and understand enclosed Pamphlet, Directions and Warnings before using.

Inactive ingredients

(See enclosed Pamphlet)

Questions or comments?

Call toll-free 1-888-373-8831 Monday - Friday 9:00 AM - 4:30 PM CT or visit us at www.conceptlabs.org

Manufactured by Concept Laboratories, Inc.
Chicago, IL 60622

Made in USA

#PV9714

NDC # 64058-116-34

PURE VALLEY® FADE CREME SKIN LIGHTENING

Drug Facts

Active ingredient

Hydroquinone 1.5%

Purpose

Skin Lightener

Uses for the gradual fading of dark (brownish) discolorations in the skin such as ■ freckles ■ age and liver spots ■ pigment in the skin that may occur in pregnancy or from the use of oral contraceptives

Warnings

For external use only.

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severe, stop use and consult a doctor

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Keep out of reach of children.

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Directions

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Inactive ingredients

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Other Information

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- 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 darkening from reoccurring.

Questions or comments? Call 1-888-373-8831 or visit www.conceptlabs.org

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#BG-PV9714

PURE VALLEY MIRACLE AGE SPOT

hydroquinone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64058-116
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	0.015 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PETROLATUM (UNII: 4T6H12BN9U)	

MINERAL OIL (UNII: T5L8T28FGP)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
SHEA BUTTER (UNII: K49155WL9Y)
GLYCERIN (UNII: PDC6A3C0OX)
Water (UNII: 059QF0K00R)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)
GLYCOLIC ACID (UNII: 0WT12SX38S)
DMDM HYDANTOIN (UNII: BYR0546TOW)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
METHYLPARABEN (UNII: A2I8C7HI9T)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
EDETATE DISODIUM (UNII: 7FLD91C86K)
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)
SODIUM METABISULFITE (UNII: 4VON5FNS3C)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64058-116-34	113 g in 1 JAR; Type 0: Not a Combination Product	10/01/2002	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part358A	10/01/2002	

Labeler - Concept Laboratories, Inc. (962282612)

Establishment

Name	Address	ID/FEI	Business Operations
Concept Laboratories, Inc.		962282612	MANUFACTURE(64058-116)

Revised: 10/2017

Concept Laboratories, Inc.