

EB5 AGE SPOT TREATMENT- hydroquinone cream
Elements Brands, 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.

EB5 Age Spot Treatment

Drug Facts

Active ingredient

Hydroquinone 2%

Purpose

Skin lightener

Uses

Lightens dark spots in the skin such as freckles, age spots and liver spots.

Warnings

- For external use only.
- Avoid contact with eyes or eyelids.
- Some users of this product may experience mild skin irritation. Consult physician if skin irritation becomes severe.

Do not use

- on children under 12, unless directed by physician

Keep out of reach of children.

If swallowed, contact physician or poison control center immediately.

Store at room temperature.

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.
- Children under 12 years of age: do not use unless directed by a doctor.
- Sun exposure should be limited by using a sunscreen agent or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from recurring.

Other Ingredients:

Acer Saccharum (Sugar Maple) Extract, Aminomethyl Propanol, Aqua (Deionized Water), Argania Spinosa (Argan) Oil, Caprylic/Capric/Myristic/Stearic Triglyceride, Carbomer, Cetearyl Alcohol, Citrus Aurantium Dulcis (Orange) Oil, Citrus Medica Limonum (Lemon) Extract, Coco-

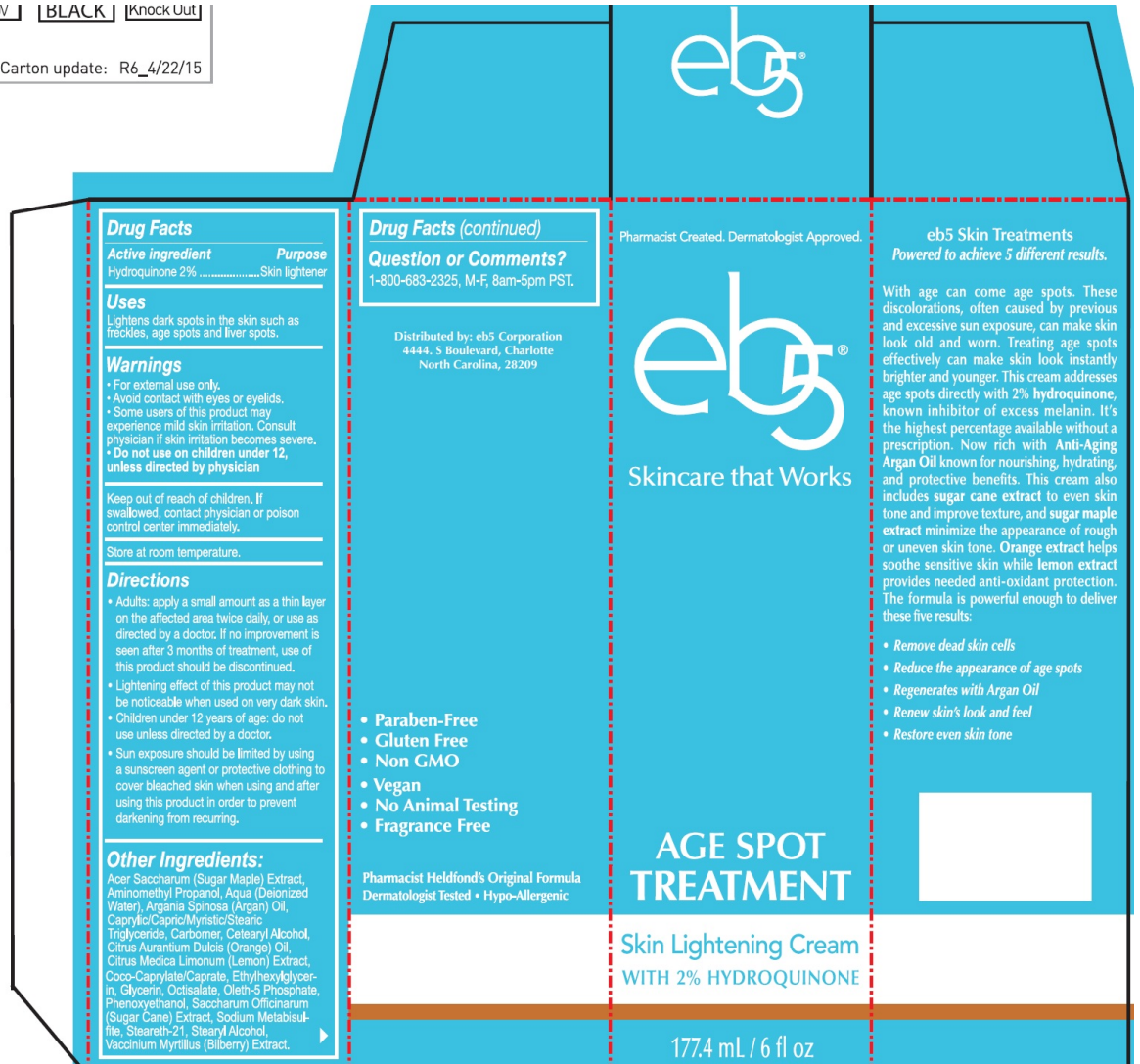
Caprylate/Caprates, Ethylhexylglycerin, Glycerin, Octisalate, Oleth-5 Phosphate, Phenoxyethanol, Saccharum Officinatum (Sugar Cane) Extract, Sodium Metabisulfite, Steareth-21, Stearyl Alcohol, Vaccinium Myrtillus (Bilberry) Extract.

Question of Comments?

1-800-683-2325, M-F, 8am-5pm PST.

Package Labeling:

10145 | PMS 637 | Salin UV | BLACK | Knock Out
NO FOIL Last Carton update: R6_4/22/15



• Adults: apply a thin layer on the affected areas twice daily, or as directed by a physician.
 • If no improvement is seen after three months of treatment, discontinue use of this product and consult physician.
 • Lightening effect of this product may be less noticeable on very dark skin.
 • Children under 12 years of age: Do not use this product unless directed by physician.
 • Sun exposure should be limited by using sunscreen agent, sun blocking agent, or protective clothing to cover bleached skin when using, and after using this product, in order to prevent darkening from reoccurring.

EB5 AGE SPOT TREATMENT			
hydroquinone cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71221-995
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	20 mg in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
WATER (UNII: 059QF0KO0R)	
ARGAN OIL (UNII: 4V59G5UW9X)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
ORANGE (UNII: 5EVU04N5QU)	
LEMON (UNII: 24RS0A988O)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
OCTISALATE (UNII: 4X49Y0596W)	
OLETH-5 PHOSPHATE (UNII: 44FE98F6UX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SUGARCANE (UNII: 81H2R5AOH3)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
STEARETH-21 (UNII: 53J3F32P58)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
BILBERRY (UNII: 9P2U39H18W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71221-995-06	1 in 1 BOX	12/15/2018	
1		177.4 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	12/15/2018	

Labeler - Elements Brands, Inc. (006166707)

Revised: 12/2018

Elements Brands, Inc.