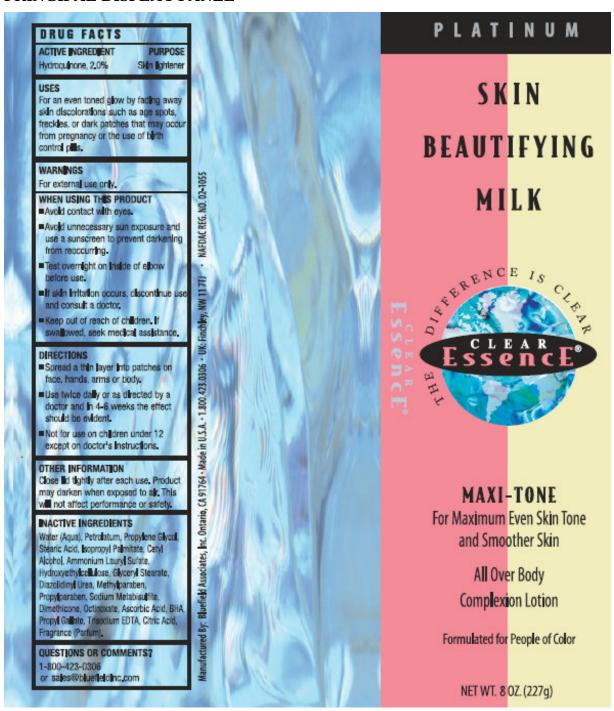
# SKIN BEAUTIFYING MILK- hydroquinone cream Bluefield Associates, Inc.

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.

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# **Skin Beautifying Milk**

#### PRINCIPAL DISPLAY PANEL



### **Active Ingredient**

Hydroquinone 2.0%

# Purpose

Skin Lightener

#### Uses:

• For an even toned glow by fading away skin discolorations such as age spots, freckles, or dark patches that may occur from pregnancy or the use of birth control pills.

# Warnings

# For External use only.

#### WHEN USING THIS PRODUCT

- Avoid contact with eyes.
- Avoid unnecessary sun exposure and use a sunscreen to prevent darkening from reoccuring.
- Test overnight on Inside of elbow before use.
- If skin irritation occurs, discontinue use and consult a doctor.

#### Do Not use on

children under 12 years of age unless directed by a doctor.

#### Keep out of the reach of children.

If swallowed, seek medical assistance.

#### **Questions or Comments?**

1-800-423-0306 or sales@bluefieldInc.com

#### Directions

- Spread a thin layer into patches on face, hands, arms or body...
- Use twice daily or as directed by a doctor and in 4-6 weeks the effect should be evident.
- Not for use on children under 12 except on doctor's intructions.

#### OTHER INFORMATION

Close lid tightly after each use. Product may darken when exposed to air. This will not affect performance or safety.

#### **Inactive Ingredients**

Water (Aqua), White Petrolatum, Cetyl Alcohol, Isopropyl Palmitate, Stearic Acid, Propylene Glycol, Stearic Acid, Ammonium Lauryl Sulfate, Dimethicone, Diazolidinyl Urea, Methylparaben, Propylparaben, Glyceryl Stearate, Sodium Metabisulfite, Ascorbic Acid, BHA, Propul Gallate, Trisodium EDTA, Fragrance (Parfum).

#### SKIN BEAUTIFYING MILK

hydroquinone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16708-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HYDRO Q UINO NE (UNII: XV74C1N1AE) (HYDRO Q UINO NE - UNII: XV74C1N1AE)	HYDROQUINONE	0.02 g in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
ASCORBIC ACID (UNII: PQ6CK8PD0R)		
PROPYL GALLATE (UNII: 8 D4SNN7V92)		
WATER (UNII: 059QF0KO0R)		
EDETATE TRISO DIUM (UNII: 420 IP9 21MB)		
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
SODIUM METABISULFITE (UNII: 4VON5FNS3C)		
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
PETROLATUM (UNII: 4T6H12BN9U)		

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:16708-001-01	1 in 1 BOX		
1	227 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
OTC monograph not final	part358 A	10/27/2015	

# Labeler - Bluefield Associates, Inc. (626594667)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bluefield Associates, Inc.		626594667	manufacture(16708-001)	

Revised: 10/2015 Bluefield Associates, Inc.