MEDICATED FADE CREME WITH SUNSCREEN- hydroquinone and octinoxate 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.

Medicated Fade Creme with Sunscreen

PRINCIPAL DISPLAY PANEL

Active Ingredient

Hydroquinone U.S.P. 2%

Purpose

Skin Lightener

Active Ingredient

Octinoxate 2.5%

Purpose

Sunscreen

Uses:

- Lightens dark discolorations on the skin such as age spots, dark patches or freckles that may occur from medication, pregnancy or exposure to the elements.
- Contains a sunscreen to help prevent darkening from reoccurring.

Warnings

For External use only. Avoid contact with eyes. 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.

Keep out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away. **If pregnant or breast-feeding,** ask a doctor before use.

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.

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).

MEDICATED FADE CREME WITH SUNSCREEN

hydroquinone and octinoxate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:16708-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	0.02 g in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.025 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16708-002-01	1 in 1 BOX		
1		113.5 g in 1 JAR; 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	10/26/2015	

Labeler - Bluefield Associates, Inc. (626594667)

Establishment

Name	Address	ID/FEI	Business Operations
Bluefield Associates, Inc.		626594667	manufacture(16708-002)

Revised: 10/2015 Bluefield Associates, Inc.