# CLEAR-N-SMOOTH- ultimate skin lightening cream cream Hawknad Manufacturing Industries

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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# Listing for Clear-N-Smooth ULTIMATE Skin Lightening Cream

# **Indications for Use**

- Lightens dark colorations in the skin such as freckles, age, and liver spots
- Contains a sunscreen to help prevent darkening from re-occurring.

# **Purpose**

Skin Lightening Cream

### Dosage

Moisten a cotton ball and apply a thin layer over the entire affected area.

# **Keep Out of Reach of Children**

Children under 12 years of age: do not use unless directed by a doctor.

# **Warnings**

Do not use on children under 12 years of age unless directed by a doctor.

This product is not for use for the prevention of sunburn.

When using this product avoid contact with eyes.

Some users of this product may experience a mild skin irritation. If irritation becomes severe, stop use and consult a doctor.

#### Instructions for Use

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. Sun exposure should be limited by using a sunscreen agent, a protective clothing to cover bleached skin after treatment is completed in order to prevent darkening from re-occurring.

# **Inactive Ingredients**

ascorbic acid, cetyl alcohol, citric acid, diazolidinyl urea, dimethicone, disodium EDTA, Fragrance, glyceryl stearate, isopropyl myristate, lanolin alcohol, methyl paraben, propyl paraben, mineral oil, propylene glycol, sodium lauryl sulfate, sodium metabisulfite, stearyl alcohol, stearyl stearate, tocopherol acetate, glabridin, water.

### **Active Ingredient**

Hydroquinone - 2%

# **Principal Display Panel**



# **CLEAR-N-SMOOTH**

ultimate skin lightening cream cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76445-0415
Route of Administration	TOPICAL		

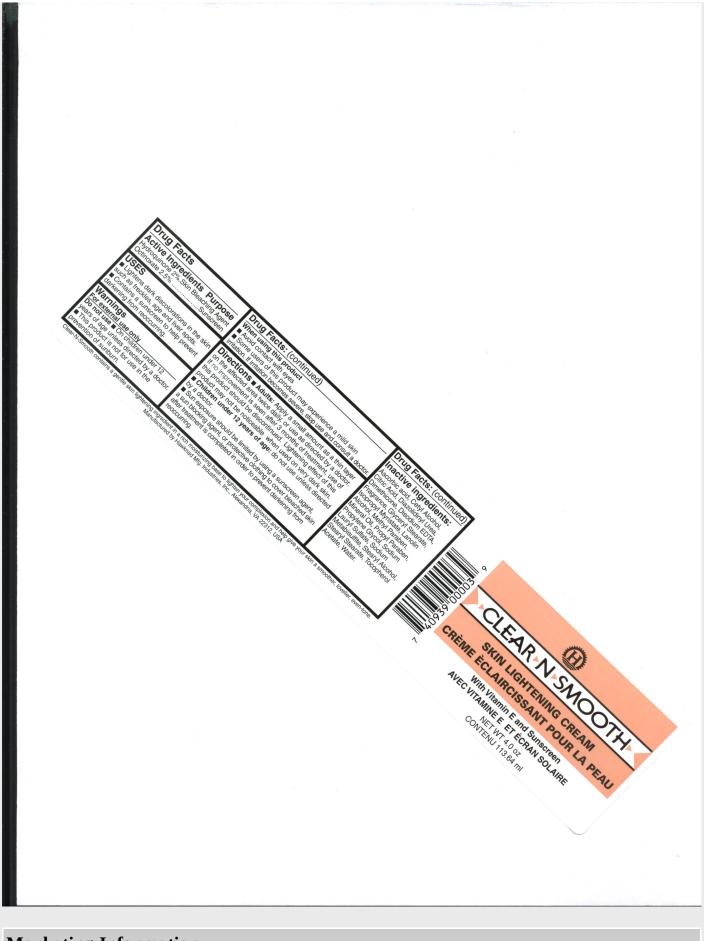
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	2 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	8.1 g in 100 g		
SODIUM LAURYL SULFATE (UNII: 368 GB5141J)	0.3 g in 100 g		
STEARYL STEARATE (UNII: 5WX2EGD0DK)	1.5 g in 100 g		
STEARYL ALCOHOL (UNII: 2KR8914H1Y)	3.5 g in 100 g		
CETYL ALCOHOL (UNII: 936JST6JCN)	3.5 g in 100 g		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	4 g in 100 g		
DIMETHICO NE 350 (UNII: 2Y53S6ATLU)	1 g in 100 g		
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)	$0.25 \; g \; \; \text{in} \; 100 \; g$		
OCTINOXATE (UNII: 4Y5P7MUD51)	3 g in 100 g		
LIGHT MINERAL OIL (UNII: N6K5787QVP)	4 g in 100 g		
ETHYLHEXYL PALMITATE (UNII: 2865993309)	2 g in 100 g		
PEG-100 STEARATE (UNII: YD01N1999R)	$2\ dL$ in $100\ g$		
ASCORBIC ACID (UNII: PQ6CK8PD0R)	0.1 g in 100 g		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	0.1 g in 100 g		
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	0.3 g in 100 g		
METHYLPARABEN (UNII: A2I8C7HI9T)	0.1 g in 100 g		
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.1 g in 100 g		
DIAZO LIDINYL UREA (UNII: H5RIZ3MPW4)	0.2 g in 100 g		
WATER (UNII: 059QF0KO0R)	57.6 g in 100 g		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	5.6 g in 100 g		

EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	0.1 g in 100 g
GLABRIDIN (UNII: HOC5567T41)	0.08 g in 100 g

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:76445-0415-4	118 g in 1 JAR; Type 0: Not a Combination Product	01/15/2001	



OTC monograph not final	part358 A	01/02/1992	

# Labeler - Hawknad Manufacturing Industries (618892426)

# **Registrant** - Hawknad Manufacturing Industries (618892426)

Establishment			
Name	Address	ID/FEI	Business Operations
EMS Acquisition Group		048602791	manufacture (76445-0415)

Revised: 12/2019 Hawknad Manufacturing Industries