

SKIN LIGHTENING COMPLEX- hydroquinone cream
G.S. COSMECEUTICAL USA, 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.

A&D pharma
Skin
Lightening
Complex
with GLYCOLIC ACID

Drug Facts

Active ingredients

Hydroquinone (2.0%)

Purpose

skin lightener

Indications

- reduce dark blotches and spots
- even out skin tone and reduce skin discoloration

Warnings

For external use only

Avoid eye contact

Discontinue use if irritation occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Apply a thin coat to the affected area twice daily or as directed by your physician
- Utilize sunscreen daily

Inactive Ingredients

Aqua (Water), Glycolic Acid, Caprylic/Capric Triglyceride, Glycerin, Cetyl Alcohol, Stearyl Alcohol, C12-C15 Alkyl Benzoate, Hydroxypropyl Starch Phosphate, Dimethicone, Sodium Hydroxide, Myristyl Alcohol, Glyceryl Stearate, Butyl Octyl Salicylate, Myristyl Glucoside, PEG 100 Stearate, Lactic Acid, Dehydroxanthan Gum, Sodium Metabisulfite, Camellia Oleifera Leaf Extract, Butylene Glycol, Camellia Sinensis Leaf Extract, Propylene Glycol, Phenoxy ethanol, Glycyrrhiza Glabra (Licorice) Root Extract, Arctostaphylos Uva Ursi Leaf Extract, Tocopheryl Acetate, BHT, Diazolidinyl Urea, Methylparaben, Propylparaben, Ethylparaben, Butylparaben, Isobutylparaben, Disodium EDTA.

Other Information

- Read directions and warnings before use
- Store at room temperature 68°-77° F (20°-25° C)

Distributed by:

A&D Pharma LLC

PRINCIPAL DISPLAY PANEL - 30 g Tube Label

**A&D
pharma**

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30 g



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A&D Pharma LLC
SAMPLE NOT FOR RESALE

10-1011

SKIN LIGHTENING COMPLEX

hydroquinone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65113-8401
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (PHENOL - UNII:339NCG44TV)	HYDROQUINONE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycolic Acid (UNII: 0WT12SX38S)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Glycerin (UNII: PDC6A3C0OX)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Stearyl Alcohol (UNII: 2KR89I4HIY)	
C12-15 Alkyl Benzoate (UNII: A9EJ3J61HQ)	
Dimethicone (UNII: 92RU3N3Y1O)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Myristyl Alcohol (UNII: V42034O9PU)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Polyoxyl 100 Stearate (UNII: YD01N1999R)	
Lactic Acid (UNII: 33X04XA5AT)	
Sodium Metabisulfite (UNII: 4VON5FNS3C)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Green Tea Leaf (UNII: W2ZU1RY8B0)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Glycyrrhiza Glabra (UNII: 2788Z9758H)	
Arctostaphylos Uva-Ursi Leaf (UNII: 3M5V3D1X36)	
Alpha-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Diazolidinyl Urea (UNII: H5RIZ3MPW4)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Ethylparaben (UNII: 14255EXE39)	
Butylparaben (UNII: 3QP1I1U3FV8)	
Isobutylparaben (UNII: 0QQJ25X58G)	
Edetate Disodium (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65113-8401-1	30 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part358A	12/09/2009	

Labeler - G.S. COSMECEUTICAL USA, INC. (017014734)

Establishment

Name	Address	ID/FEI	Business Operations
G.S. COSMECEUTICAL USA, INC.		017014734	MANUFACTURE

Revised: 9/2010

G.S. COSMECEUTICAL USA, INC.