

VIVIDLY BRILLIANT PERFECTING- hydroquinone liquid
AMCOL Health & Beauty Solutions, Inc. DBA

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.

Vividly Brilliant Perfecting Lotion

HBS Code (Labeler): FP60402-50.2

Distributor: Derma Faith

Human Prescription Drug

Active Ingredient: Hydroquinone 4%

CARTON TEXT

vividly brilliant
perfecting lotion

derma faith

50 ml/1.7 fl oz

vividly brilliant
perfecting lotion

Directions:

Apply a single pump to face in the evening. If you have never used a retinol product before, begin by limiting use to twice a week, gradually increasing frequency to every other night, and then advancing to each evening or as tolerated. Mild redness, peeling and irritation is expected when using this product.

Use daily sun protection during use of this product. Avoid getting in eyes. If contact occurs, rinse eyes thoroughly with water.

Caution:

Do not use if you are pregnant, lactating or planning to become pregnant.

Keep out of reach of children.

Derma Faith LLC
5701 W. Slaughter Lane
A130 #337
Austin, TX 78749
Made in the U.S.A.
www.dermafaith.com
M050839

This extra-strength formula features patented MICROSPPONGE® Technology to gently, yet effectively help reduce the appearance of dark spots and fine lines.

Active Ingredients:

Hydroquinone 4.0%

Inactive Ingredients:

Water, Caprylic/Capric, Triglyceride, Cetearyl Alcohol, Glycerin, Polysorbate 60, Dimethicone, Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer, C10-30 Cholesterol/Lanosterol Esters, Cetyl Ricinoleate, Cetyl Alcohol, Benzyl Alcohol, Polyacrylamide, Cetyl Phosphate, Sodium Metabisulfite, TEA-Stearate, Phenoxyethanol, Magnesium Aluminum Silicate, Cyclopentasiloxane, Triethanolamine, C13-14 Isoparaffin, PEG-10 Soy Sterol, Cyclohexasiloxane, Disodium EDTA, Methylparaben, Retinol, Polysorbate 20, Laureth-7, Bisabolol, Ascorbic Acid, Tocopheryl Acetate, BHT, Ascorbyl Palmitate, Propyl Gallate

150609

AMCOL Health & Beauty Solutions, Inc. DBA
301 Laser Lane Lafayette, LA 70507 | www.amcolhpc.com
lauren.haase@amcol.com

Principal Display Panel - Carton Label

vividly brilliant

perfecting lotion

derma

faith

50 ml/1.7 fl oz

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Principal Display Panel - Bottle Label

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hydroquinone liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68634-051
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
hydroquinone (UNII: XV74C1N1AE) (hydroquinone - UNII:XV74C1N1AE)	hydroquinone	40 g in 2 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
glycerin (UNII: PDC6A3C0OX)	
polysorbate 60 (UNII: CAL22UVI4M)	
dimethicone (UNII: 92RU3N3Y1O)	
methyl methacrylate/glycol dimethacrylate crosspolymer (UNII: EG97988M5Q)	
C10-30 cholesterol/lanosterol esters (UNII: 137SL7IL0Y)	
cetyl ricinoleate (UNII: 1P677500YD)	

cetyl alcohol (UNII: 936JST6JCN)
benzyl alcohol (UNII: LKG8494WBH)
cetyl phosphate (UNII: VT07D6X67O)
sodium metabisulfite (UNII: 4VON5FNS3C)
trolamine Stearate (UNII: 1J6JM3JE61)
phenoxyethanol (UNII: HIE492ZZ3T)
magnesium aluminum silicate (UNII: 6M3P64V0NC)
cyclomethicone 5 (UNII: 0THT5PCI0R)
trolamine (UNII: 9O3K93S3TK)
C13-14 isoparaffin (UNII: E4F12ROE70)
PEG-10 soy sterol (UNII: FG54K98L0Q)
cyclomethicone 6 (UNII: XHK3U310BA)
edetate disodium (UNII: 7FLD91C86K)
methylparaben (UNII: A2I8C7HI9T)
retinol (UNII: G2SH0XKK91)
polysorbate 20 (UNII: 7T1F30V5YH)
Laureth-7 (UNII: Z95S6G8201)
levomenol (UNII: 24WE03BX2T)
ascorbic acid (UNII: PQ6CK8PD0R)
.alpha.-tocopherol acetate, DL- (UNII: WR1WPI7EW8)
butylated hydroxytoluene (UNII: 1P9D0Z171K)
ascorbyl palmitate (UNII: QN83US2B0N)
propyl gallate (UNII: 8D4SNN7V92)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68634-051-01	1 in 1 CARTON		
1		50 mL 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	01/01/2015	

Labeler - AMCOL Health & Beauty Solutions, Inc. DBA (872684803)

Establishment			
Name	Address	ID/FEI	Business Operations
AMCOL Household & Personal Care		872684803	MANUFACTURE(68634-051) , PACK(68634-051) , LABEL(68634-051) , ANALYSIS(68634-051)