

ZO SKIN HEALTH PIGMENT CONTROL PLUS BRIGHTENING CREME
HYDROQUINONE PLUS VITAMIN C- hydroquinone emulsion
ZO Skin Health, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

PIGMENT CONTROL + BRIGHTENING CRÈME
4% Hydroquinone + 20% Vitamin C

DOSAGE AND ADMINISTRATION

Apply 2 pumps (1g) to affected areas twice a day or as directed by a physician. Always use sunscreen protection. (See enclosed package insert for full prescribing information.)

WARNINGS

Keep out of reach of children. For external use only. Avoid contact with the eyes. Some users may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a physician. Do not use on children under 12 years of age unless directed by a physician. If swallowed, get medical help or contact a Poison Control Center right away.

STORAGE

Store at controlled room temperature: 15°-30°C (59°-86°F), away from direct sunlight.

ACTIVE INGREDIENT

Hydroquinone 4%

INACTIVE INGREDIENTS

Ascorbic Acid, Ascorbyl Palmitate, Caprylic/Capric Triglyceride, Caprylyl Methicone, Cetyl PEG/PPG-10/1 Dimethicone, Dimethicone, Dimethicone Crosspolymer, Ethoxydiglycol, Helianthus Annuus (Sunflower) Seed Oil, Oleyl Alcohol, Plukenetia Volubilis Seed Oil, Retinyl Palmitate, Rosmarinus Officinalis (Rosemary) Leaf Extract, Squalane, Tocopherol, Tocopheryl Acetate, Zanthoxylum Bungeanum Fruit Extract.

Bleaches and corrects the most severe and advanced forms of hyperpigmentation in the skin with 4% hydroquinone and 20% vitamin C.

Dist. by ZO Skin Health, Inc. Irvine, CA 92618

Made in USA with US & imported materials zoskinhealth.com | 906000

PRINCIPAL DISPLAY PANEL - 81 mL Bottle Carton

ZO[®] SKIN HEALTH
BY ZEIN OBAGI MD

PIGMENT CONTROL +
BRIGHTENING CRÈME

4% Hydroquinone
+ 20% Vitamin C

RX ONLY

NDC 42851-035-81

81 mL / 2.7 Fl. Oz.



BRIGHTENING

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ZO SKIN HEALTH PIGMENT CONTROL PLUS BRIGHTENING CREME HYDROQUINONE PLUS VITAMIN C

hydroquinone emulsion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42851-035
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydroquinone (UNII: XV74C1N1AE) (Hydroquinone - UNII:XV74C1N1AE)	Hydroquinone	0.04 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Ascorbic Acid (UNII: PQ6CK8PD0R)	
Ascorbyl Palmitate (UNII: QN83US2B0N)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Caprylyl Trisiloxane (UNII: Q95M2P1KJL)	
Cetyl PEG/PPG-10/1 Dimethicone (HLB 2) (UNII: V2W71V8T0X)	
Dimethicone (UNII: 92RU3N3Y1O)	
Dimethicone Crosspolymer (450000 MPAS AT 12% IN Cyclopentasiloxane) (UNII: UF7620L1W6)	
Diethylene Glycol Monoethyl Ether (UNII: A1A1I8X02B)	
Sunflower Oil (UNII: 3W1JG795YI)	
Oleyl Alcohol (UNII: 172F2WN8DV)	
Plukenetia Volubilis Seed Oil (UNII: 8ED72Z8J1Z)	
Vitamin A Palmitate (UNII: 1D1K0N0VVC)	
Rosemary (UNII: IJ67X351P9)	
Squalane (UNII: GW89575KF9)	
Tocopherol (UNII: R0ZB2556P8)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Zanthoxylum Bungeanum Fruit (UNII: 3CIP16A418)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-035-81	1 in 1 CARTON	05/01/2018	
1		81 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		05/01/2018	

Labeler - ZO Skin Health, Inc. (826468527)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	ANALYSIS(42851-035) , LABEL(42851-035) , MANUFACTURE(42851-035) , PACK(42851-035) , RELABEL(42851-035) , REPACK(42851-035)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		080095015	LABEL(42851-035) , MANUFACTURE(42851-035) , PACK(42851-035) , RELABEL(42851-035) , REPACK(42851-035)

Revised: 4/2019

ZO Skin Health, Inc.