ZO SKIN HEALTH PIGMENT CONTROL CREME HYDROQUINONE-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.

ZO® Skin Health Pigment Control Crème 4% Hydroquinone
National Drug Codes 42851-037-80, 42851-037-30

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. Contains Sodium Metabisulfite, a sulfite that may cause serious allergic-type reactions, including anaphylactic symptoms (e.g., hives, itching) and life-threatening or less-severe asthmatic episodes in certain susceptible persons. 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.

SUNBURN ALERT

This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing, and limit sun exposure while using this product and for a week afterward.

STORAGE

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

ACTIVE INGREDIENT

Hydroquinone 4%

INACTIVE INGREDIENTS

Aqua/Water/Eau, Ascorbic Acid, Ascorbyl Palmitate, Beta-Glucan, Caprylyl Glycol, Cetyl Alcohol, Chlorphenesin, Dioscorea Villosa (Wild Yam) Root Extract, Disodium EDTA, Glycerin, Glycolic Acid, Phenoxyethanol, Quillaja Saponaria Bark Extract, Smilax Aristolochiifolia Root Extract, Sodium Hydroxide, Sodium Lauryl Sulfate, Sodium

Metabisulfite, Sodium Sulfite, Stearyl Alcohol, Tocopheryl Acetate, Yucca Schidigera Root Extract.

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

PRINCIPAL DISPLAY PANEL - 80 mL Bottle Carton

ZO ® SKIN HEALTH
BY ZEIN OBAGI MD

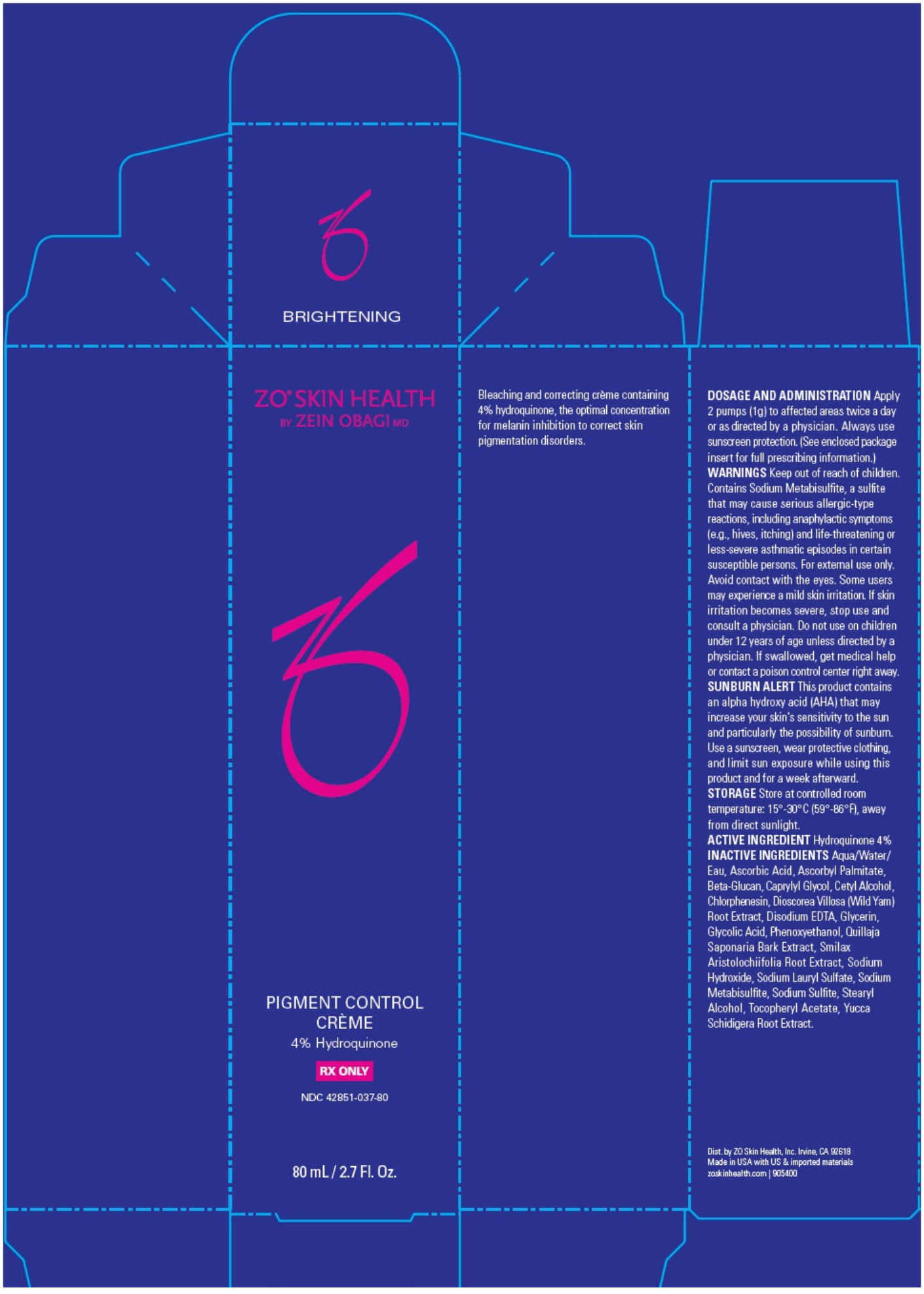
PIGMENT CONTROL
CRÈME

4% Hydroquinone

RX ONLY

NDC 42851-037-80

80 mL / 2.7 Fl. Oz.


BRIGHTENING
ZO® SKIN HEALTH
BY ZEIN OBAGI MD
Bleaching and correcting crème containing 4% hydroquinone, the optimal concentration for melanin inhibition to correct skin pigmentation disorders.
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.)
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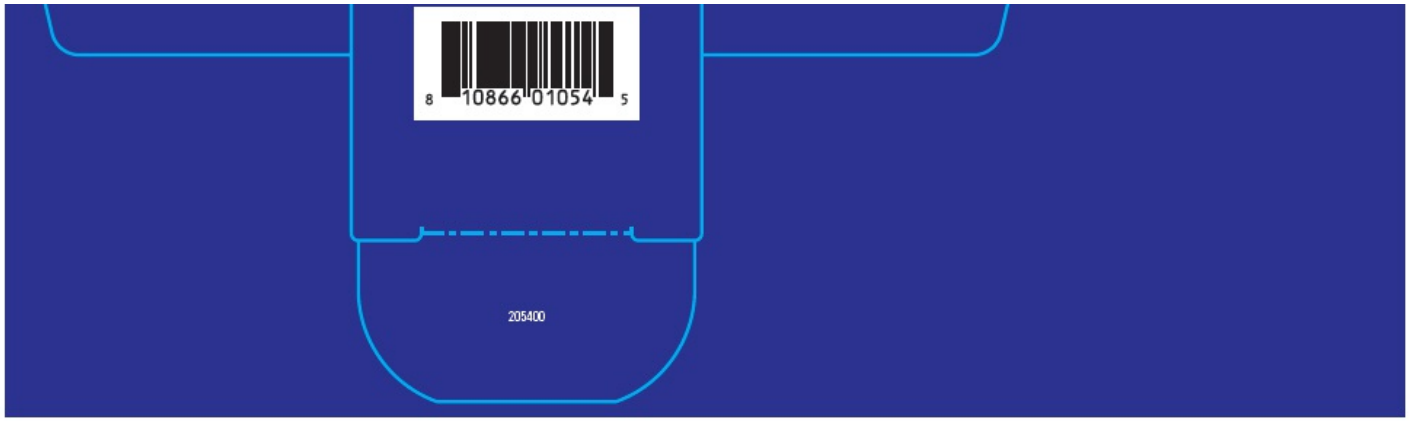
PIGMENT CONTROL CRÈME
4% Hydroquinone
RX ONLY
NDC 42851-037-80
80 mL / 2.7 Fl. Oz.
Dist. by ZO Skin Health, Inc. Irvine, CA 92618
Made in USA with US & imported materials
zoskinhealth.com | 905400



ZO SKIN HEALTH PIGMENT CONTROL CREME HYDROQUINONE

hydroquinone emulsion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42851-037
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	40 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIOSCOREA VILLOSA TUBER (UNII: IWY3IWX2G8)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
QUILLAJA SAPONARIA BARK (UNII: 8N0K3807ZW)	
SMILAX ARISTOLOCHIIFOLIA ROOT (UNII: NR100Y25G0)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM SULFITE (UNII: VTK01UQK3G)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-037-80	1 in 1 CARTON	04/15/2018	
1		80 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:42851-037-30	1 in 1 CARTON	07/01/2018	
2		30 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		04/15/2018	

Labeler - ZO Skin Health, Inc. (826468527)

Revised: 4/2022 ZO Skin Health, Inc.