# ZO SKIN HEALTH PIGMENT CONTROL PLUS BLENDING CREME HYDROQUINONE- hydroquinone lotion ZO Skin Health, 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.

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# ZO <sup>®</sup> Skin Health Pigment Control + Blending Crème 2% Hydroquinone National Drug Code 42851-039-80

## **Drug Facts**

## **Active Ingredient**

Hydroquinone, 2%

## **Purpose**

Skin Lightener

#### Uses

For the gradual fading of (or lightens) dark (or brownish) discolorations in the skin such as freckles, age spots, pigment in the skin that may occur in pregnancy or from the use of oral contraceptives.

## Warnings

# For external use only.

Avoid contact with eyes.

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

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

# Keep out of reach of children.

If swallowed, seek medical help or contact a Poison Control Center right away.

#### **Directions**

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

 Sun exposure should be limited by using a sunscreen agent or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

### Other Information

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

# **Inactive Ingredients**

Aqua/Water/Eau, Ascorbic Acid, Ascorbyl Palmitate, Beta-Glucan, Caprylyl Glycol, Cetyl Alcohol, Chlorphenesin, Dioscorea Villosa (Wild Yam) Root Extract, Disodium EDTA, Ethylhexyl Palmitate, Glycerin, Glycolic Acid, Palmitic Acid, Phenoxyethanol, Phenyl Trimethicone, 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

### Questions?

5 Technology Dr. Irvine, CA 92618

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

#### PRINCIPAL DISPLAY PANEL - 80 mL Bottle Carton

ZO <sup>®</sup> SKIN HEALTH BY ZEIN OBAGI MD

NDC 42851-039-80

PIGMENT CONTROL + BLENDING CRÈME 2% Hydroquinone

80 mL / 2.7 Fl. Oz.



#### Drug Facts (continued)

Glycerin, Glycolic Acid, Palmitic Grycern, Grycolic Acid, Painmic Acid, Phenoxyethanol, Phenyl Trimethicone, Quillaja Saponaria Bark Extract, Smilax Aristolochiifolia Root Extract, Sodium Hydroxide, Sodium Lauryl Sulfate, Sodium Metabisulfite, Sodium Sulfite, Stearyl Alcohol, Tocopheryl Acetate, Yucca Schidionar Root Extract Schidigera Root Extract

#### Questions?

5 Technology Dr. Irvine, CA 92618

NDC 42851-039-80

#### PIGMENT CONTROL + **BLENDING CRÈME**

2% Hydroquinone

80 mL / 2.7 Fl. Oz.

2% hydroquinone crème lessens the appearance of discoloration for a more even skin tone.

#### Drug Facts

Active Ingredient Purpose
Hydroquinone, 2%......Skin Lightener

Uses
For the gradual fading of (or lightens)
dark (or brownish) discolorations in
the skin such as freckles, age spots,
pigment in the skin that may occur in pregnancy or from the use of oral contraceptives.

#### Warnings

For external use only. Avoid contact with eyes.

Do not use on children under 12 years of age unless directed

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

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

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Inactive Ingredients
Aqua/Water/Eau, Ascorbic Acid,
Ascorbyl Palmitate, Beta-Glucan,
Caprylyl Glycol, Cetyl Alcohol,
Chlorphenesin, Dioscorea Villosa
(Wild Yam) Root Extract, Disodium
EDTA, Ethylhexyl Palmitate,

Dist. by ZO Skin Health, Inc. Irvine, CA 92618 Made in USA with US & imported materials



# ZO SKIN HEALTH PIGMENT CONTROL PLUS BLENDING CREME HYDROQUINONE

hydroquinone lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42851-039	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	20 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: 1670DAL4SZ)	
DIOSCOREA VILLOSA TUBER (UNII: IWY3IWX2G8)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
PALMITIC ACID (UNII: 2V16EO95H1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
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)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:42851- 039-80	1 in 1 CARTON	01/11/2019	09/23/2020	
1		80 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	
OTC monograph not final	part358A	01/11/2019		

# Labeler - ZO Skin Health, Inc. (826468527)

Revised: 4/2022 ZO Skin Health, Inc.