ZO SKIN HEALTH PIGMENT CONTROL PROGRAM PLUS HYDROQUINONE-hydroquinone
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 Program + Hydroquinone

(Hydroquinone USP, 4%)

NDC 42851-184-60

PIGMENT CONTROL CREME

(Hydroquinone USP, 4%)

RX ONLY

FOR EXTERNAL USE ONLY:

NOT FOR OPHTHALMIC USE

DESCRIPTION

Hydroquinone is 1,4-benzendiol, with a chemical formula of C6H6O2 and a molecular weight of 110.11.

The structural formula is:

Each gram of Pigment Control Creme (Hydroquinone USP, 4%) contains Hydroquinone USP 40 mg/gm in a base of Purified Water, 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.

CLINICAL PHARMACOLOGY

Topical application of hydroquinone produces a reversible depigmentation of the skin by inhibition of the enzymatic oxidation of tyrosine to 3,4-dihydroxyphenylalanine (DOPA) and suppression of other melanocyte metabolic processes. Exposure to sunlight or ultraviolet light will cause re-pigmentation of bleached areas, which may be prevented by the use of the sunscreen agents.

INDICATIONS AND USAGE

Pigment Control Creme is indicated in the gradual bleaching of hyperpigmentation, skin conditions such as chloasma, melasma, freckles, senile lentigines, and other unwanted areas of melanin hyperpigmentation.

CONTRAINDICATIONS

Prior history of sensitivity or allergic reaction to this product or any of its ingredients. The safety of topical Hydroquinone use during pregnancy or in children (12 years and under) has not been established.

WARNINGS

Hydroquinone is a skin bleaching agent which may produce undesired effects if not used as directed. The physician should be familiar with the contents of this insert before prescribing or dispensing this product.

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

Avoid unnecessary sun exposure, use an effective broad-spectrum sunscreen agent or protective clothing should be worn to cover bleached skin to prevent re-pigmentation from occurring.

Hydroquinone may produce exogenous ochronosis, a gradual blue-black darkening of the skin. If this condition occurs, discontinue treatment and consult your physician.

Avoid contact with eyes and mucous membranes. Keep out of reach of children. In case of accidental ingestion, call a physician or a poison control center immediately.

PRECAUTIONS

Test for skin sensitivity before using by applying a small amount to an unbroken patch of skin; check within 24 hours. Minor redness is not a contraindication, but where there is itching or vesicle formation or excessive inflammatory response, further treatment is not advised. Close patient supervision is recommended.

Drug Interactions

Patients are cautioned on concomitant use of medications that are known to be photosensitizing.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies of hydroquinone in animals have demonstrated some evidence of carcinogenicity. The carcinogenic potential of hydroquinone in humans is unknown.

Pregnancy Category C

Animal reproduction studies have not been conducted with topical hydroquinone. It is also not known whether topical hydroquinone can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Topical hydroquinone should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when topical hydroquinone is administered to a nursing woman.

Pediatric Use

Safety and effectiveness for pediatric patients below the age of 12 years have not been established.

Adverse Reactions

The following reactions have been reported: dryness and fissuring of paranasal and infraorbital areas, erythema, and stinging. Occasional hypersensitivity (localized contact dermatitis) may develop. If this occurs, the medication should be discontinued, and the physician notified immediately.

Overdosage

There have been no system reactions reported from the use of topical hydroquinone. However, treatment should be limited to relatively small areas of the body at one time, since some patients experience a transient skin reddening and a mild burning sensation which does not preclude treatment.

DRUG DOSAGE AND ADMINISTRATION

A thin layer of Pigment Control Creme (Hydroquinone USP, 4%) should be applied to the affected area twice daily or as directed by a physician. If no improvement is seen after 8-12 weeks of treatment, use of this product should be discontinued. There is no recommended dosage for pediatric patients under 12 years of age except under the advice and supervision of a physician.

HOW SUPPLIED

Pigment Control Creme (Hydroquinone USP, 4%) is available as follows:

2.7 Fl. Oz. (80 mL) Bottle / NDC 42851-037-80

1.0 fl oz/30 ml Bottle / NDC 42851-037-30

STORAGE

Store at controlled room temperature: 15°-30°C (59°-86°F)

PIGMENT CONTROL + BLENDING CREME
(Hydroquinone USP, 4%)

RX ONLY
FOR EXTERNAL USE ONLY:
NOT FOR OPHTHALMIC USE

DESCRIPTION

Hydroquinone is 1,4-benzendiol, with a chemical formula of C6H6O2 and a molecular weight of 110.11.

The structural formula is:

Each gram of Pigment Control + Blending Creme contains Hydroquinone USP 40mg/gm in a base of 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, Purified Water, 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.

CLINICAL PHARMACOLOGY

Topical application of hydroquinone produces a reversible depigmentation of the skin by inhibition of the enzymatic oxidation of tyrosine to 3,4-dihydroxyphenylalanine (DOPA) and suppression of other melanocyte metabolic processes. Exposure to sunlight or ultraviolet light will cause re-pigmentation of bleached areas, which may be prevented by the use of the sunscreen agents.

INDICATIONS AND USAGE

For the gradual bleaching of hyperpigmented skin conditions such as cholasma, melasma, freckles, senile lentigines, and other unwanted areas of melanin hyperpigmentation.

CONTRAINDICATIONS

Prior history of sensitivity or allergic reaction to hydroquinone or to any other ingredient in this product. The safety of topical hydroquinone use during pregnancy or in children (12 years and under) has not been established.

WARNINGS

Hydroquinone is a skin bleaching agent which may produce undesired effects if not used as directed. The physician should be familiar with the contents of this insert before prescribing or dispensing this product.

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

Avoid unnecessary sun exposure, use an effective broad-spectrum sunscreen agent or protective clothing should be worn to cover bleached skin to prevent re-pigmentation from occurring.

Hydroquinone may produce exogenous ochronosis, a gradual blue-black darkening of the skin. If this condition occurs, discontinue treatment and consult your physician.

Avoid contact with eyes and mucous membranes. Keep out of reach of children. In case of accidental ingestion, call a physician or a poison control center immediately.

PRECAUTIONS

Test for skin sensitivity before using by applying a small amount to an unbroken patch of skin; check within 24 hours. Minor redness is not a contraindication, but where there is itching or vesicle formation or excessive inflammatory response, further treatment is not advised. Close patient supervision is recommended.

Drug Interactions

Patients are cautioned on concomitant use of medications that are known to be photosensitizing.

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Overdosage

There have been no system reactions reported from the use of topical hydroquinone. However, treatment should be limited to relatively small areas of the body at one time, since some patients experience a transient skin reddening and a mild burning sensation which does not preclude treatment.

DRUG DOSAGE AND ADMINISTRATION

A thin application of Pigment Control + Blending Creme should be applied to the affected area twice daily or as directed by a physician. Consult product label for instructions on whether to rub in or not. There is no recommendation for children under 12 years of age except under the advice and supervision of a physician.

HOW SUPPLIED

Pigment Control + Blending Creme (Hydroquinone USP, 4%) is available as follows:

2.7 Fl. Oz. (80 mL) Bottle / NDC 42851-036-80

1.0 Fl. Oz (30 mL) Bottle / NDC 42851-036-30

STORAGE

Store at controlled room temperature: 15°-30°C (59°-86°F)

PRINCIPAL DISPLAY PANEL - Kit Carton

ZO ® SKIN HEALTH

BY ZEIN OBAGI MD

PIGMENT CONTROL PROGRAM

+ HYDROQUINONE

NDC 42851-184-60

GENTLE CLEANSER 60 mL / 2 Fl. Oz.

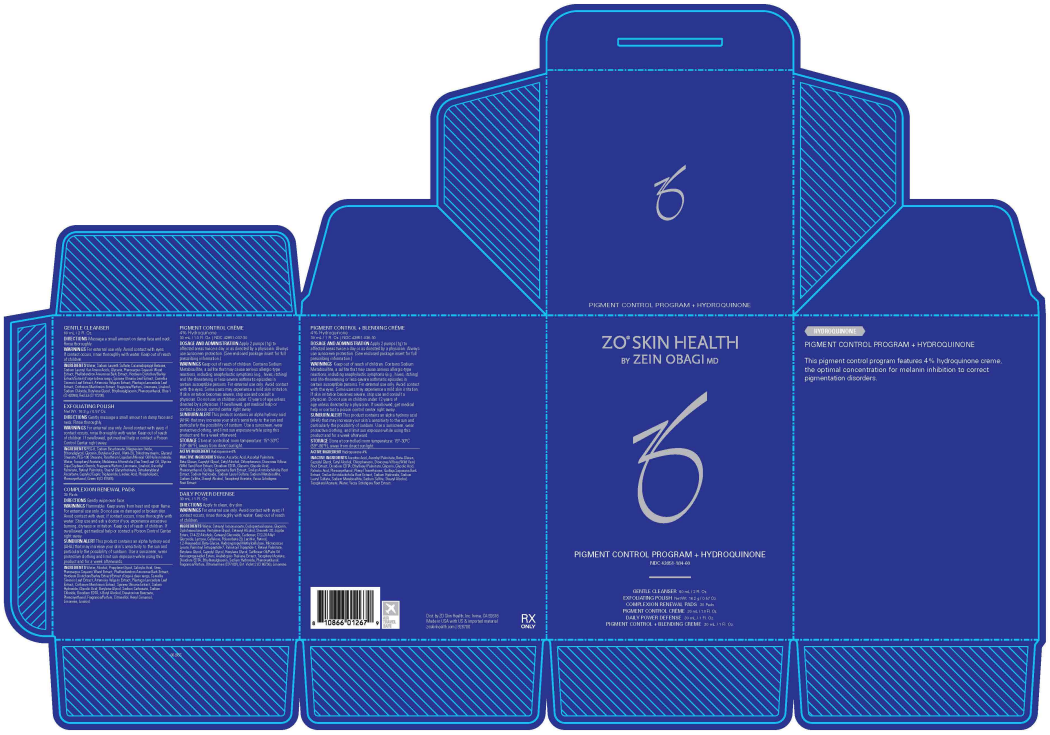
EXFOLIATING POLISH Net Wt. 16.2 g / 0.57 Oz.

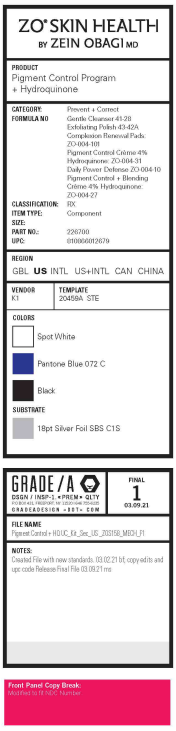
COMPLEXION RENEWAL PADS 30 Pads

PIGMENT CONTROL CRÈME 30 mL / 1.0 Fl. Oz.

DAILY POWER DEFENSE 30 mL / 1 Fl. Oz.

PIGMENT CONTROL + BLENDING CREME 30 mL / 1 Fl. Oz.





ZO SKIN HEALTH PIGMENT CONTROL PROGRAM PLUS HYDROQUINONE

hydroquinone kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42851-184

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-184-60	1 in 1 CARTON	03/09/2021	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	60 mL
Part 2	1 JAR	16.2 g
Part 3	30 JAR	30
Part 4	1 BOTTLE, PLASTIC	30 mL
Part 5	1 BOTTLE, PLASTIC	30 mL
Part 6	1 BOTTLE, PUMP	30 mL

Part 1 of 6

ZO SKIN HEALTH GENTLE CLEANSER

cleansing (cold creams, cleansing lotions, liquids, and pads) gel

Product Information	
Route of Administration	TOPICAL

Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity
INGR	**WATER** (UNII: 059QF0KO0R)	
INGR	**SODIUM LAURETH-3 SULFATE** (UNII: BPV390UAP0)	
INGR	**COCAMIDOPROPYL BETAINE** (UNII: 5OCF3O11KX)	
INGR	**SODIUM LAUROYL OAT AMINO ACIDS** (UNII: FSW2K9B9N5)	
INGR	**GLYCERIN** (UNII: PDC6A3C0OX)	
INGR	**GREEN TEA LEAF** (UNII: W2ZU1RY8B0)	
INGR	**LIMONENE, (+/-)-** (UNII: 9MC3I34447)	
INGR	**LINALOOL, (+/-)-** (UNII: D81QY6I88E)	
INGR	**SODIUM CHLORIDE** (UNII: 451W47IQ8X)	
INGR	**BUTYLENE GLYCOL** (UNII: 3XUS85K0RA)	
INGR	**ETHYLHEXYLGLYCERIN** (UNII: 147D247K3P)	
INGR	**PHENOXYETHANOL** (UNII: HIE492ZZ3T)	
INGR	**FD&C BLUE NO. 1** (UNII: H3R47K3TBD)	
INGR	**D&C RED NO. 33** (UNII: 9DBA0SBB0L)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1		60 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		03/09/2021	

Part 2 of 6

ZO SKIN HEALTH EXFOLIATING POLISH

lotions, oils, powders, and creams suspension

Product Information

Route of Administration	TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ)	
INGR	**SODIUM BICARBONATE** (UNII: 8MDF5V39QO)	
INGR	**MAGNESIUM OXIDE** (UNII: 3A3U0GI71G)	
INGR	**DIETHYLENE GLYCOL MONOETHYL ETHER** (UNII: A1A1I8X02B)	
INGR	**GLYCERIN** (UNII: PDC6A3C0OX)	
INGR	**BUTYLENE GLYCOL** (UNII: 3XUS85K0RA)	
INGR	**OLETH-20** (UNII: YTH167I2AG)	
INGR	**TRIHYDROXYSTEARIN** (UNII: 06YD7896S3)	
INGR	**GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4)	
INGR	**PEG-100 STEARATE** (UNII: YD01N1999R)	
INGR	**MINERAL OIL** (UNII: T5L8T28FGP)	
INGR	**WATER** (UNII: 059QF0KO0R)	
INGR	**.ALPHA.-TOCOPHEROL ACETATE, DL-** (UNII: WR1WPI7EW8)	
INGR	**TEA TREE OIL** (UNII: VIF565UC2G)	
INGR	**SOY STEROL** (UNII: PL360EPO9J)	
INGR	**LIMONENE, (+/-)-** (UNII: 9MC3I34447)	
INGR	**LINALOOL, (+/-)-** (UNII: D81QY6I88E)	
INGR	**ASCORBYL PALMITATE** (UNII: QN83US2B0N)	
INGR	**VITAMIN A PALMITATE** (UNII: 1D1K0N0VVC)	
INGR	**STEARYL GLYCYRRHETINATE** (UNII: 3YYE6VJS0P)	
INGR	**TETRAHEXYLDECYL ASCORBATE** (UNII: 9LBV3F07AZ)	
INGR	**MEDIUM-CHAIN TRIGLYCERIDES** (UNII: C9H2L21V7U)	
INGR	**LINOLEIC ACID** (UNII: 9KJL21T0QJ)	
INGR	**LECITHIN, SOYBEAN** (UNII: 1DI56QDM62)	
INGR	**PHENOXYETHANOL** (UNII: HIE492ZZ3T)	
INGR	**D&C GREEN NO. 6** (UNII: 4QP5U84YF7)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		16.2 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		03/09/2021	

Part 3 of 6

ZO SKIN HEALTH COMPLEXION RENEWAL PADS

cleansing (cold creams, cleansing lotions, liquids, and pads) patch

Product Information	
Route of Administration	TOPICAL

Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity
INGR	**ALCOHOL** (UNII: 3K9958V90M)	
INGR	**SALICYLIC ACID** (UNII: O414PZ4LPZ)	
INGR	**SODIUM HYDROXIDE** (UNII: 55X04QC32I)	
INGR	**GLYCOLIC ACID** (UNII: 0WT12SX38S)	
INGR	**PHENOXYETHANOL** (UNII: HIE492ZZ3T)	
INGR	**SODIUM CARBONATE** (UNII: 45P3261C7T)	
INGR	**EDETATE DISODIUM ANHYDROUS** (UNII: 8NLQ36F6MM)	
INGR	**DENATONIUM BENZOATE** (UNII: 4YK5Z54AT2)	
INGR	**.BETA.-CITRONELLOL, (R)-** (UNII: P01OUT964K)	
INGR	**.ALPHA.-HEXYLCINNAMALDEHYDE** (UNII: 7X6O37OK2I)	
INGR	**LINALOOL, (+/-)-** (UNII: D81QY6I88E)	
INGR	**UREA** (UNII: 8W8T17847W)	
INGR	**BARLEY** (UNII: 5PWM7YLI7R)	
INGR	**BUTYLENE GLYCOL** (UNII: 3XUS85K0RA)	
INGR	**SODIUM CHLORIDE** (UNII: 451W47IQ8X)	
INGR	**TERT-BUTYL ALCOHOL** (UNII: MD83SFE959)	
INGR	**PTEROCARPUS SOYAUXII WOOD** (UNII: 0V6QB4C61P)	
INGR	**GREEN TEA LEAF** (UNII: W2ZU1RY8B0)	
INGR	**LIMONENE, (+)-** (UNII: GFD7C86Q1W)	
INGR	**WATER** (UNII: 059QF0KO0R)	
INGR	**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)	

INGR	**PLANTAGO LANCEOLATA LEAF** (UNII: 2YWL9J7EE8)	
INGR	**PHELLODENDRON AMURENSE BARK** (UNII: PBG27B754G)	
INGR	**CRITHMUM MARITIMUM** (UNII: J7IHY79BKY)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		03/09/2021	

Part 4 of 6

ZO SKIN HEALTH PIGMENT CONTROL CREME HYDROQUINONE

hydroquinone emulsion

Product Information	
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		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		03/09/2021	

Part 5 of 6

ZO SKIN HEALTH PIGMENT CONTROL PLUS BLENDING CREME HYDROQUINONE

hydroquinone emulsion

Product Information

Item Code (Source)	NDC:42851-036
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	0.04 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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)	
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)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
WATER (UNII: 059QF0KO0R)	
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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		03/09/2021	

Part 6 of 6

ZO SKIN HEALTH DAILY POWER DEFENSE

other skin care preparations lotion

Product Information

Route of Administration	TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**PENTYLENE GLYCOL** (UNII: 50C1307PZG)	
INGR	**POWDERED CELLULOSE** (UNII: SMD1X3XO9M)	

INGR	**RETINOL** (UNII: G2SH0XKK91)	
INGR	**LIMONENE, (+)-** (UNII: GFD7C86Q1W)	
INGR	**CETOSTEARYL ALCOHOL** (UNII: 2DMT128M1S)	
INGR	**C12-20 ALKYL GLUCOSIDE** (UNII: K67N5Z1RUA)	
INGR	**LACTOSE, UNSPECIFIED FORM** (UNII: J2B2A4N98G)	
INGR	**BUTYLENE GLYCOL** (UNII: 3XUS85K0RA)	
INGR	**HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO)	
INGR	**PALMITOYL TETRAPEPTIDE-7** (UNII: Q41S464P1R)	
INGR	**PALMITOYL TRIPEPTIDE-1** (UNII: RV743D216M)	
INGR	**CAPRYLYL GLYCOL** (UNII: 00YIU5438U)	
INGR	**STEARETH-20** (UNII: L0Q8IK9E08)	
INGR	**.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0)	
INGR	**CYCLOMETHICONE 5** (UNII: 0THT5PCI0R)	
INGR	**GLYCERIN** (UNII: PDC6A3C0OX)	
INGR	**CETEARYL ISONONANOATE** (UNII: P5O01U99NI)	
INGR	**CYCLOMETHICONE 6** (UNII: XHK3U310BA)	
INGR	**PHENOXYETHANOL** (UNII: HIE492ZZ3T)	
INGR	**EXT. D&C VIOLET NO. 2** (UNII: G5UX3K0728)	
INGR	**EDETATE DISODIUM ANHYDROUS** (UNII: 8NLQ36F6MM)	
INGR	**SODIUM HYDROXIDE** (UNII: 55X04QC32I)	
INGR	**ETHYLHEXYLGLYCERIN** (UNII: 147D247K3P)	
INGR	**VITAMIN A PALMITATE** (UNII: 1D1K0N0VVC)	
INGR	**HEXYLENE GLYCOL** (UNII: KEH0A3F75J)	
INGR	**ARABIDOPSIS THALIANA** (UNII: AI3L60HQ81)	
INGR	**ULTRAMARINE BLUE** (UNII: I39WR998BI)	
INGR	**1,2-HEXANEDIOL** (UNII: TR046Y3K1G)	
INGR	**C14-22 ALCOHOLS** (UNII: B1K89384RJ)	
INGR	**CETEARYL GLUCOSIDE** (UNII: 09FUA47KNA)	
INGR	**CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE** (UNII: 0A5MM307FC)	
INGR	**WATER** (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		03/09/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug		03/09/2021	

other		03/09/2021	

Labeler - ZO Skin Health, Inc. (826468527)

Revised: 4/2022 ZO Skin Health, Inc.