

**ZO MEDICAL ZO NON-HYDROQUINONE HYPERPIGMENTATION SYSTEM FOR SKIN
BRIGHTENING- titanium dioxide
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.

**ZO[®] MEDICAL ZO[®] NON-HYDROQUINONE HYPERPIGMENTATION SYSTEM For Skin
Brightening**

Drug Facts

Active ingredient

Titanium Dioxide 8%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only.

Do not use on damaged or broken skin.

Stop and ask a doctor if rash occurs.

When using this product keep out of eyes. Rinse with water to remove.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Other information

- Store product in a cool place away from direct heat and sunlight.
- You may report a serious adverse reaction to: 5 Technology Dr. #100, Irvine, CA 92618

Directions

- For full protection, apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- For children under 6 months of age: ask a doctor.
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk regularly use a sunscreen with a broad spectrum SPF value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 a.m.- 2 p.m.

- Wear long-sleeved shirts, pants, hats and sunglasses.
- Apply to all skin exposed to the sun.

Inactive ingredients

Water, Aluminum Hydroxide, Stearic Acid, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Cyclopentasiloxane, Phenyl Trimethicone, Styrene/Acrylates Copolymer, Pentylene Glycol, Dimethicone, Glycerin, Isodecyl Neopentanoate, Diisopropyl Sebacate, Lauryl Lactate, Polyacrylamide, Disodium EDTA, Phytosphingosine, Cetareth-20, Cetaryl Alcohol, PEG-100 Stearate, Glyceryl Stearate, Sodium Dihydroxycetyl Phosphate, Hydrogenated Palm Glycerides, Melanin, Ethylhexylglycerin, Erythritol, Homarine HCL, Sodium Benzoate, Potassium Sorbate, Phenoxyethanol, Caprylyl Glycol, Chlorphenesin, Nephelium Lappaceum Peel Extract, Glycine Soja (Soybean) extract, Silica, C13-14 Isoparaffin, Laureth-7.

DIST BY

ZO Skin Health, Inc. Irvine, CA 92618

PRINCIPAL DISPLAY PANEL - Kit Carton

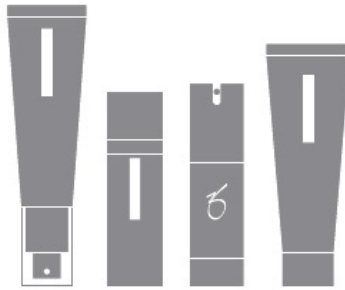
ZO[®] MEDICAL
BY ZEIN OBAGI MD

NDC 42851-158-60

ZO[®] NON-HYDROQUINONE HYPERPIGMENTATION SYSTEM

For Skin Brightening

For Skin Brightening



ZO® NON-HYDROQUINONE HYPERPIGMENTATION SYSTEM

For Skin Brightening

ZO MEDICAL ZO NON-HYDROQUINONE HYPERPIGMENTATION SYSTEM FOR SKIN BRIGHTENING

titanium dioxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42851-158
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-158-60	1 in 1 CARTON	11/01/2015	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE, WITH APPLICATOR	50 mL
Part 2	1 TUBE	30 mL
Part 3	1 BOTTLE, PUMP	30 mL
Part 4	1 TUBE	60 g

Part 1 of 4

ZO MEDICAL C-BRIGHT SERUM VITAMIN C

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

Product Information

Route of Administration

TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Cyclomethicone 5 (UNII: 0THT5PCI0R)	
INGR	Ascorbic Acid (UNII: PQ6CK8PD0R)	
INGR	Dimethicone Crosspolymer (450000 Mpa.S At 12% In Cyclopentasiloxane) (UNII: UF7620L1W6)	
INGR	Dimethicone (UNII: 92RU3N3Y1O)	
INGR	Phenoxyethanol (UNII: HIE492ZZ3T)	
INGR	Bitter Orange Oil (UNII: 9TLV70SV6I)	
INGR	Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ)	
INGR	Squalane (UNII: GW89575KF9)	
INGR	.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
INGR	Ubidecarenone (UNII: EJ27X76M46)	
INGR	Limonene, (+)- (UNII: GFD7C86Q1W)	
INGR	Citral (UNII: T7EU0O9VPP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		50 mL in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		11/01/2015	

Part 2 of 4**ZO MEDICAL BRIGHTALIVE NON-RETINOL SKIN BRIGHTENER**

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

Product Information

Route of Administration

TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Water (UNII: 059QF0KO0R)	

INGR	Cyclomethicone 5 (UNII: 0THT5PCI0R)	
INGR	Caprylyl Trisiloxane (UNII: Q95M2P1KJL)	
INGR	Glycerin (UNII: PDC6A3C0OX)	
INGR	Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
INGR	Alpha-Arbutin (UNII: 72VUP07IT5)	
INGR	Bellis Perennis Flower (UNII: 26I94X9A1K)	
INGR	Glyceryl Monostearate (UNII: 230OU9XXE4)	
INGR	PEG-100 Stearate (UNII: YD01N1999R)	
INGR	Cetyl Alcohol (UNII: 936JST6JCN)	
INGR	Nonapeptide-1 (UNII: 64W45420K5)	
INGR	Dimethylmethoxy Chromanyl Palmitate (UNII: 5G222ZDK7U)	
INGR	Ubidecarenone (UNII: EJ27X76M46)	
INGR	Hexylresorcinol (UNII: R9QTB5E82N)	
INGR	Glycyrrhiza Glabra (UNII: 2788Z9758H)	
INGR	Sunflower Oil (UNII: 3W1JG795YI)	
INGR	Rosemary (UNII: IJ67X351P9)	
INGR	Olea Europaea Leaf (UNII: MJ95C3OH47)	
INGR	Stachys Officinalis Flowering Top (UNII: D7A759WU38)	
INGR	Maltodextrin (UNII: 7CVR7L4A2D)	
INGR	Lecithin, Sunflower (UNII: 834K0WOS5G)	
INGR	Soy Isoflavones (UNII: 71B37NR06D)	
INGR	Polysorbate 80 (UNII: 6OZP39ZG8H)	
INGR	Alcohol (UNII: 3K9958V90M)	
INGR	Ascorbyl Glucoside (UNII: 2V52R0NHXW)	
INGR	Zinc Pidolate (UNII: C32PQ86DH4)	
INGR	Ascorbic Acid (UNII: PQ6CK8PD0R)	
INGR	N-Acetylglucosamine (UNII: V956696549)	
INGR	Hydrogenated Soybean Lecithin (UNII: H1109Z9J4N)	
INGR	Sodium Oleate (UNII: 399SL044HN)	
INGR	Butylene Glycol (UNII: 3XUS85K0RA)	
INGR	N-Acetyltyrosine (UNII: DA8G610ZO5)	
INGR	Proline (UNII: 9DLQ4CIU6V)	
INGR	Adenosine Triphosphate (UNII: 8L70Q75FXE)	
INGR	Papain (UNII: A236A06Y32)	
INGR	Carboxypolymethylene (UNII: 0A5MM307FC)	
INGR	1,2-Hexanediol (UNII: TR046Y3K1G)	
INGR	Sodium Alginate (UNII: C269C4G2ZQ)	
INGR	Poly(Methyl Methacrylate; 450000 MW) (UNII: Z47NNT4J11)	
INGR	.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
INGR	Vitamin A Palmitate (UNII: 1D1K0N0VVC)	
INGR	Ascorbyl Palmitate (UNII: QN83US2B0N)	
INGR	Sodium Sulfite (UNII: VTK01UQK3G)	
INGR	Polyisobutylene (1000 MW) (UNII: 5XB3A63Y52)	
INGR	Polysorbate 20 (UNII: 7T1F30V5YH)	
INGR	PEG-12 Dimethicone/PPG-20 Crosspolymer (UNII: 965K72OQXO)	
INGR	Dextran 1 (UNII: I8LHQ0D645)	
INGR	Edetate Disodium (UNII: 7FLD91C86K)	
INGR	Phenoxyethanol (UNII: HIE492ZZ3T)	
INGR	Caprylyl Glycol (UNII: 00YIU5438U)	
INGR	Chlorphenesin (UNII: I670DAL4SZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 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		11/01/2015	

Part 3 of 4

ZO SKIN HEALTH OSSENTIAL DAILY POWER DEFENSE

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

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Water (UNII: 059QF0KO0R)	
INGR	Cetearyl Isononanoate (UNII: P5O01U99NI)	
INGR	Cyclomethicone 5 (UNII: 0THT5PCI0R)	
INGR	Cyclomethicone 6 (UNII: XHK3U310BA)	
INGR	Pentylene Glycol (UNII: 50C1307PZG)	
INGR	Cetostearyl Alcohol (UNII: 2DMT128MIS)	
INGR	Glycerin (UNII: PDC6A3C0OX)	
INGR	Steareth-20 (UNII: L0Q8IK9E08)	
INGR	Carboxypolymethylene (UNII: 0A5MM307FC)	
INGR	C14-22 Alcohols (UNII: B1K89384RJ)	
INGR	Phenoxyethanol (UNII: HIE492ZZ3T)	
INGR	Cetearyl Glucoside (UNII: 09FUA47KNA)	
INGR	Polysorbate 20 (UNII: 7T1F30V5YH)	
INGR	Butylene Glycol (UNII: 3XUS85K0RA)	
INGR	Palmitoyl Tetrapeptide-7 (UNII: Q41S464P1R)	
INGR	Sodium Hydroxide (UNII: 55X04QC32I)	
INGR	Caprylyl Glycol (UNII: 00YIU5438U)	
INGR	C12-20 Alkyl Glucoside (UNII: K67N5Z1RUA)	
INGR	Ethylhexylglycerin (UNII: 147D247K3P)	
INGR	Lactose, Unspecified Form (UNII: J2B2A4N98G)	
INGR	Edetate Disodium (UNII: 7FLD91C86K)	
INGR	Powdered Cellulose (UNII: SMD1X3XO9M)	
INGR	Hexylene Glycol (UNII: KEH0A3F75J)	
INGR	Potassium Sorbate (UNII: 1VPU26JZZ4)	

INGR	1,2-Hexanediol (UNII: TR046Y3K1G)	
INGR	Methylparaben (UNII: A2I8C7HI9T)	
INGR	Lecithin, Sunflower (UNII: 834K0WOS5G)	
INGR	Hypromelloses (UNII: 3NXW29V3WO)	
INGR	Sorbitol (UNII: 506T60A25R)	
INGR	Edetic Acid (UNII: 9G34HU7RV0)	
INGR	Benzoic Acid (UNII: 8SKN0B0MIM)	
INGR	Sodium Benzoate (UNII: OJ245FE5EU)	
INGR	Arabidopsis Thaliana (UNII: A3L60HQ81)	
INGR	Retinol (UNII: G2SH0XKK91)	
INGR	Vitamin A Palmitate (UNII: 1D1K0N0VVC)	
INGR	.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
INGR	Orange Oil (UNII: AKN3KSD11B)	
INGR	Lemon Oil (UNII: I9GRO824LL)	
INGR	Mandarin Oil (UNII: NJO720F72R)	
INGR	Peppermint Oil (UNII: AV092KU4JH)	
INGR	Mimosa Tenuiflora Bark (UNII: 515MQE449I)	
INGR	Tocopherol (UNII: R0ZB2556P8)	
INGR	Limonene, (+)- (UNII: GFD7C86Q1W)	
INGR	Ultramarine Blue (UNII: I39WR998BI)	
INGR	Ext. D&C Violet No. 2 (UNII: G5UX3K0728)	

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		11/01/2015	

Part 4 of 4

ZO MEDICAL OCLIPSE-C BROAD-SPECTRUM SUNSCREEN SPF 50

titanium dioxide lotion

Product Information

Item Code (Source)	NDC:42851-052
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.08 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Aluminum Hydroxide (UNII: 5QB0T2IUN0)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Polyglyceryl-3 Polydimethylsiloxylethyl Dimethicone (4000 MPA.S) (UNII: RLA2U05Z4Q)	
Cyclomethicone 5 (UNII: 0THT5PC10R)	
Phenyl Trimethicone (UNII: DR0K5NOJ4R)	
Pentylene Glycol (UNII: 50C1307PZG)	
Dimethicone (UNII: 92RU3N3Y1O)	
Glycerin (UNII: PDC6A3C0OX)	
Isodecyl Neopentanoate (UNII: W60VYE24XC)	
Diisopropyl Sebacate (UNII: J8T3X564IH)	
Lauryl Lactate (UNII: G5SU0BFK7O)	
Edetate Disodium (UNII: 7FLD91C86K)	
Phytosphingosine (UNII: GIN46U9Q2Q)	
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWUY)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
PEG-100 Stearate (UNII: YD01N1999R)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Sodium Dihydroxycetyl Phosphate (UNII: YW133EV595)	
Hydrogenated Palm Glycerides (UNII: YCZ8EM144Q)	
Melanin Synthetic (Tyrosine, Peroxide) (UNII: O0CV1RMR44)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Erythritol (UNII: RA96B954X6)	
Homarine Hydrochloride (UNII: 8866LNG61N)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Chlorphenesin (UNII: I670DAL4SZ)	
Nephelium Lappaceum Fruit Rind (UNII: Y0513T90FO)	
Soybean (UNII: L7HT8F1ZOD)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
C13-14 Isoparaffin (UNII: E4F12ROE70)	
Laureth-7 (UNII: Z95S6G8201)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-052-60	60 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/01/2015	

Labeler - ZO Skin Health, Inc. (826468527)

Establishment

Name	Address	ID/FEI	Business Operations
Milbar Laboratories, Inc.		195556790	MANUFACTURE(42851-158)

Establishment

Name	Address	ID/FEI	Business Operations
G.S. COSMECEUTICAL USA, INC.		017014734	MANUFACTURE(42851-158)

Establishment

Name	Address	ID/FEI	Business Operations
PakLab		790530976	MANUFACTURE(42851-158)

Establishment

Name	Address	ID/FEI	Business Operations
Thibiant International, Inc.		083913913	MANUFACTURE(42851-158)

Revised: 7/2016

ZO Skin Health, Inc.