

ZO SKIN HEALTH RENEW- 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[®] SKIN HEALTH RENEW

Drug Facts

Active ingredients

Titanium Dioxide 8.2%

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

When using this product

- keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

- rash occurs

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

Directions

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- children under 6 months of age: ask a doctor
- reapply at least every two hours
- **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

Other information

- protect this product from excessive heat and direct sun
- You may report a serious adverse reaction to: 5 Technology Dr. Irvine, CA 92618

Inactive ingredients

Cyclopentasiloxane, Dimethicone Crosspolymer, Phenyl Trimethicone, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Stearic Acid, Aluminum Hydroxide, Dimethicone/Vinyl Dimethicone Crosspolymer, Tribehenin, Water, Helianthus Annuus (Sunflower) Seed Oil, Polymethyl Methacrylate, Polyglyceryl-4 Isostearate, Hexyl Laurate, Cetyl PEG/PPG-10/1 Dimethicone, Glycerin, Dimethiconol, Cyclotetrasiloxane, Squalane, Caprylic/Capric Triglyceride, Tocopheryl Acetate, Melanin, Behenyl Behenate, Triethoxycaprylylsilane, Polyglyceryl-5 Trioleate, Ethyl Ferulate, Glycine Soja (Soybean) Seed Extract, Calcium Chloride, Retinyl Palmitate, Pentylene Glycol, Methylisothiazolinone, Ascorbic Acid, Rosmarinus Officinalis (Rosemary) Leaf Extract, Phenoxyethanol, Potassium Sorbate, Ethylhexylglycerin, Myristoyl Pentapeptide-8, Tocopherol, Disodium Uridine Phosphate, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Iron Oxides.

DIST BY ZO Skin Health, Inc. Irvine, CA 92618

PRINCIPAL DISPLAY PANEL - Kit Carton

ZO[®] SKIN HEALTH
BY ZEIN OBAGI MD

RE NEW

OFFECTS[®] HYDRATING CLEANSER
40 mL / 1.5 Fl. Oz.

OFFECTS[®] EXFOLIATING POLISH
Net Wt. 16.2 g / 0.57 Oz.

OCLIPSE[®] SUNSCREEN + PRIMER
BROAD-SPECTRUM SPF 30
15 mL / 0.5 Fl. Oz.

NDC 42851-163-01

Comprehensive Skin Health Solutions
from Zein Obagi, MD



ZO° SKIN HEALTH
BY ZEIN OBAGI MD

RENEW

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OCLIPSE® SUNSCREEN + PRIMER BROAD-SPECTRUM SPF 30	15 mL / 0.5 Fl. Oz.

NDC 42851-163-01

Start your day off
with renewed skin!

Cleanse your skin with Effects® Hydrating Cleanser,
Exfoliate with Effects® Exfoliating Polish and
Protect with Oclipse® Sunscreen + Primer SPF 30.



EFFECTS® HYDRATING CLEANSER

40 mL / 1.5 Fl. Oz.

Moisten hands with lukewarm water; apply a small amount to damp face and neck. To help increase penetration of the ingredients, rub one minute. Rinse thoroughly.

INGREDIENTS Water, Sodium Cocoyl Isethionate, Sodium Methyl Cocoyl Taurate, Glycerin, Stearic Acid, Glyceryl Stearate, PEG-10 Stearate, Glycol Distearate, Disodium Cocoamphodiacetate, Cetyl Alcohol, Phenoxyethanol, Acrylates Copolymer, Sodium Chloride, Panthenol, Fragrance, Urea, Sodium PCA, Sodium Hydroxide, Trehalose, Ethylhexylglycerin, Sodium Glycolate, Cocoyl Hydroxyethyl Imidazoline, Triacetin, Chlorphenesin, Potassium Sorbate, Sodium Hyaluronate, Sorbic Acid, Polyquaternium-51, Allantoin, Red 33, Yellow 6.

OCLIPSE® SUNSCREEN + PRIMER (BROAD-SPECTRUM SPF 30 UVA/UVB PROTECTION)

15 mL / 0.5 Fl. Oz. (NDC 42851-053-01)

Drug Facts	
Active ingredients	Purpose
Titanium Dioxide 8.2%	Sunscreen
Uses	
<ul style="list-style-type: none"> helps prevent sunburn. if used as directed with other sun protection measures (see <i>Directions</i>), 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	
When using this product	
• keep out of eyes. Rinse with water to remove.	
Stop use and ask a doctor if • rash occurs	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away	
Directions	
<ul style="list-style-type: none"> apply liberally 15 minutes before sun exposure use a water resistant sunscreen if swimming or sweating children under 6 months of age: ask a doctor reapply at least every two hours 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:	
<ul style="list-style-type: none"> limit time in the sun, especially from 10 a.m.-2 p.m. wear long-sleeved shirts, pants, hats and sunglasses 	
Other information	
<ul style="list-style-type: none"> protect this product from excessive heat and direct sun You may report a serious adverse reaction to: 5 Technology Dr. Irvine, CA 92618 	
Inactive ingredients	
Cyclopentasiloxane, Dimethicone Crosspolymer, Phenyl Trimethicone, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Stearic Acid, Aluminum Hydroxide, Dimethicone/Vinyl Dimethicone Crosspolymer, Tribehenin, Water, Helianthus Annuus (Sunflower) Seed Oil, Polymethyl Methacrylate, Polyglyceryl-4 Isostearate, Hexyl Laurate, Cetyl PEG/PPG-10/1 Dimethicone, Glycerin, Dimethiconol, Cyclotetrasiloxane, Squalane, Caprylic/Capric Triglyceride, Tocopheryl Acetate, Melanin, Behenyl Behenate, Triethoxycaprylylsilane, Polyglyceryl-5 Trioleate, Ethyl Ferulate, Glycine Soja (Soybean) Seed Extract, Calcium Chloride, Retinyl Palmitate, Pentylene Glycol, Methylisothiazolinone, Ascorbic Acid, Rosmarinus Officinalis (Rosemary) Leaf Extract, Phenoxyethanol, Potassium Sorbate, Ethylhexylglycerin, Myristoyl Pentapeptide-8, Tocopherol, Disodium Uridine Phosphate, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Iron Oxides.	

EFFECTS® EXFOLIATING POLISH

Net Wt. 16.2 g / 0.57 Oz.

After cleansing, moisten face with lukewarm water. Apply a small amount to damp face and neck. Massage skin in a circular motion; adding water as necessary. Rinse thoroughly. Use at least twice a week, morning or evening.

INGREDIENTS PEG-8, Sodium Bicarbonate, Ethoxydiglycol, Magnesium Oxide, Glycerin, Oleth-20, Glyceryl Stearate, Trihydroxystearin, PEG-100 Stearate, Tocopheryl Acetate, Tetrahexyldecyl Ascorbate, Retinyl Palmitate, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Ascorbyl Palmitate, Fragrance, Stearyl Glycyrrhetinate, Propylparaben, Phospholipids, Linoleic Acid, Glycine Soja (Soybean) Sterols, Caprylic/Capric Triglyceride, Green 6.

CAUTION Stop use if rash or irritation develops and persists. Keep out of eyes. Keep out of reach of children. Products may make your skin more sensitive to the sun; wear a sunscreen with SPF 30 daily.

DIST BY ZO Skin Health, Inc. Irvine, CA 92618
"ZO" is a registered trademark of ZO Skin Health, Inc.
MADE IN USA 094900

zoskinhealth.com

**ZO SKIN HEALTH RENEW**

titanium dioxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42851-163
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-163-01	1 in 1 CARTON	12/01/2015	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	40 mL
Part 2	1 JAR	16.2 g
Part 3	1 BOTTLE, PUMP	15 mL

Part 1 of 3

ZO SKIN HEALTH EFFECTS HYDRATING CLEANSER

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	SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
INGR	SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	STEARIC ACID (UNII: 4ELV7Z65AP)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	PEG-100 STEARATE (UNII: YD01N1999R)	
INGR	GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
INGR	DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	PANTHENOL (UNII: WV9CM0O67Z)	
INGR	UREA (UNII: 8W8T17847W)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	TREHALOSE (UNII: B8WCK70T7I)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	SODIUM GLYCOLATE (UNII: B75E535IM)	
INGR	TRIACETIN (UNII: XHX3C3X673)	
INGR	CHLORPHENESIN (UNII: I670DAL4SZ)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	SORBIC ACID (UNII: X045WJ989B)	
INGR	POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
INGR	ALLANTOIN (UNII: 344S277G0Z)	
INGR	D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
INGR	FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		40 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		12/01/2015	

Part 2 of 3

ZO SKIN HEALTH EFFECTS EXFOLIATING POLISH

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

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	DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
INGR	MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	OLETH-20 (UNII: YTH167I2AG)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	
INGR	PEG-100 STEARATE (UNII: YD01N1999R)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
INGR	VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
INGR	TEA TREE OIL (UNII: VIF565UC2G)	
INGR	ASCORBYL PALMITATE (UNII: QN83US2B0N)	
INGR	STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
INGR	LINOLEIC ACID (UNII: 9KJL21T0QJ)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
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		12/01/2015	

Part 3 of 3

ZO SKIN HEALTH OCLIPSE SUNSCREEN PLUS PRIMER BROAD-SPECTRUM SPF 30 UVA/UVB PROTECTION

titanium dioxide lotion

Product Information

Item Code (Source) NDC:42851-053

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	82 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0TH15PC10R)	
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPAS) (UNII: RLA2U05Z4Q)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
WATER (UNII: 059QF0K00R)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONOL (100000 CST) (UNII: OSA9UP217S)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
SQUALANE (UNII: GW89575KF9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MELANIN SYNTHETIC (TYROSINE, PEROXIDE) (UNII: O0CV1RMR44)	
BEHENYL BEHENATE (UNII: K8NU647RJ0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ETHYL FERULATE (UNII: 5B8915UELW)	
SOYBEAN (UNII: L7HT8F1ZOD)	

CALCIUM CHLORIDE (UNII: M4I0D6VV5M)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
ROSEMARY (UNII: IJ67X351P9)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
TOCOPHEROL (UNII: R0ZB2556P8)
URIDINE MONOPHOSPHATE DISODIUM (UNII: KD8E20071T)
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-053-01	15 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
OTC monograph final	part352	12/01/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/01/2015	

Labeler - ZO Skin Health, Inc. (826468527)

Establishment			
Name	Address	ID/FEI	Business Operations
Lifetech Resources, LLC.		081239587	manufacture(42851-163)

Establishment			
Name	Address	ID/FEI	Business Operations
Thibiant International, Inc.		083913913	manufacture(42851-163)