

ZO MEDICAL 3-STEP PEEL KIT - oatmeal
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 3-STEP PEEL[™] Kit

Drug Facts

Active ingredient

Colloidal Oatmeal, 1%

Purpose

Skin Protectant

Uses

Temporarily protects and helps relieve minor skin irritation and itching due to:

- rashes.

Warnings

For external use only

When using this product

- do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of the reach of children

Directions

apply as needed

Inactive ingredients

Water, Glycerin, Petrolatum, Distearyltrimonium Chloride, Isopropyl Palmitate, Cyclopentasiloxane, Cetyl Alcohol, Butyrospermum Parkii (Shea) Butter, Benzyl Alcohol, Polymethyl Methacrylate, Dipotassium Glycyrrhizate, Benzalkonium Chloride, Butylene Glycol, Tocopheryl Acetate, Pentylene Glycol, 1,2-Hexanediol, Sodium Chloride, Alcohol, Isopropyl Alcohol, Beta-Glucan, Retinyl Palmitate, Ascorbic Acid, Dibenzyl Ether, Tetrapeptide-21, Myristoyl Pentapeptide-11.

DIST BY

ZO Skin Health, Inc.
Irvine, CA 92618

PRINCIPAL DISPLAY PANEL - Kit Carton

ZO[®]MEDICAL

BY ZEIN OBAGI MD

NDC 42851-190-56

ZO[®] 3-STEP PEEL™

KIT

FOR PROFESSIONAL USE ONLY

6 treatments

PART OF DR. OBA GI'S ZO® SKIN HEALTH CIRCLÉ™



ZO®MEDICAL
BY ZEIN OBA GI MD

NDC 42851-190-56

ZO® 3-STEP PEEL™
KIT

FOR PROFESSIONAL USE ONLY

6 treatments



The ZO® 3-Step Peel™ is an enhancing peel that supports both ZO® Medical therapeutic systems and ZO® Skin Health daily skincare programs to enhance and extend their benefits. It is designed to be performed as a series of treatments for continuous skin health restoration and rejuvenation.

This exclusive blend of potent exfoliants: 17% salicylic acid, 10% trichloroacetic acid and 5% lactic acid remove the outermost layers of the skin. 6% Retinol Crème Complex confers longer lasting benefits beyond the temporary superficial improvements seen with ordinary peels. Peeling is mild, with minimal to no downtime. Designed for acne, melasma, sun damage, fine lines and wrinkles, rough texture, large pores and dullness. This peel promotes softer, smoother, firmer skin.

- Suitable for any skin type or color
- Usage studies show remarkable safety with minimal irritation
- Can be repeated every 3-4 weeks if deeper repair is desired

The ZO® 3-Step Peel™ is designed to:

1. Remove the outermost layers of skin (Peel Solution) to improve color tone, texture and smoothness.
2. Stimulate deeper skin layers for more profound benefits, stimulating cellular function (6% Retinol Crème Complex).
3. Suppress skin irritation that can be caused by peels, sun, hormones and pollution post-procedure (Revitrol™ Epidermal Repair Crème Skin Protectant).

Recommendations for use:

The ZO® 3-Step Peel™ can be repeated every 3-4 weeks to improve skin's elasticity, texture and tone.

Indicated for conditions of acne, PIH, melasma, sun damage, fine lines, texture roughness, large pores and dullness.

3SP

FOR PROFESSIONAL USE ONLY

3-step in-office peel procedure to improve color, tone, texture, smoothness and stimulate cellular function.

KIT CONTENTS

- Peel Solution (8 mL / 0.27 Fl. Oz.) - qty. 6
- Retinol Crème Complex Packets (Net Wt. 2.5 g / 0.09 Oz.) - qty. 12
- Revitratol™ Epidermal Repair Crème Skin Protectant (Net Wt. 58 g / 2.0 Oz.) - qty. 6
- Applicators (non-woven pads) - qty. 18
- ZO® 3-Step Peel™ Technical Booklet - qty. 1
- Patient Guidelines - qty. 6

INSTRUCTIONS

See enclosed ZO® 3-Step Peel™ Technical Booklet as written by Zein Obagi, MD.

WARNINGS

The procedure for and use of the 3-Step Peel™ can only be performed by a licensed physician or, if permitted by law, a properly trained specialist working under a physician's supervision. Proper medical knowledge is essential to performing any TCA peel. The treating physician is responsible for informing a patient about potential medical risks and complications.

The Peel Solution (TCA, lactic and salicylic acids) is very acidic which can cause severe burns. The 6% Retinol Crème Complex is of a very high concentration and can cause irritation. Keep the Peel Solution and 6% Retinol Crème Complex away from children and do not put in open wounds or eyes.

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 afterwards.

INGREDIENTS

Peel Solution Alcohol, Salicylic Acid, Trichloroacetic Acid, Water (Aqua), Lactic Acid, Ethoxydiglycol, Water, t-Butyl Alcohol, Denatonium Benzoate, Yellow 5 (CI 19140).

Retinol Crème Complex Water (Aqua, Eau), Caprylic/Capric Triglyceride, Polysorbate 20, Retinol, Glycerin, Allyl Methacrylates, Crosspolymer, Stearyl Alcohol, Polysorbate 80, Glyceryl Stearate, Butyrospermum Parkii Butter, Butylene Glycol, Cyclopentasiloxane, Palmitic Acid, Ubiquinone, Triethanolamine, Tocopheryl Acetate, Hydrogenated Jojoba Oil, Dipotassium Glycyrrhizate, Dimethicone, Carbomer, BHT, Disodium EDTA, Stearic Acid, Bisabolol, Beta-Glucan, Ascorbic Acid, Sorbitol, Phenoxyethanol, Cyclohexylsiloxane, Cyclohexylsiloxane, Cyclohexasiloxane, Camellia Sinensis Leaf Extract, Sodium Hyaluronate, Carthamus Tinctorius Seed Oil, Calendula Officinalis Flower Extract, Myristoyl Tripeptide-4, Chamomilla Recutita Flower Extract, Xanthan Gum, Mammidium Vulgare Meristem Cell Culture, Leontopodium Alpinum Meristem Cell Culture, Hexylene Glycol, Ethylhexylglycerin, Caprylyl Glycol, BHA, Dimethicone/Vinyl Dimethicone Crosspolymer, Malus Domestica Fruit Water, Myristic Acid, Glyceryl Acrylate/Acrylic Acid Copolymer, Lecithin.

Revitratol™ Epidermal Repair Crème Skin Protectant
Net Wt. 58 g / 2.0 Oz. (NDC 42951-083-56)

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Colloidal Oatmeal, 1%	Skin Protectant

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

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of ZO Skin Health, Inc.
MADE IN USA 095800

zoskinhealth.com

ZS1800-01

ZO MEDICAL 3-STEP PEEL KIT

oatmeal kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42851-190
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-190-56	1 in 1 CARTON	12/01/2016	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 BOTTLE, DISPENSING	48 mL
Part 2	12 PACKET	30 g
Part 3	6 TUBE	348 mL

Part 1 of 3**ZO MEDICAL PEEL**

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

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Alcohol (UNII: 3K9958V90M)	
INGR	Salicylic Acid (UNII: O414PZ4LPZ)	
INGR	Trichloroacetic Acid (UNII: 5V2JDO056X)	
INGR	Water (UNII: 059QF0K00R)	
INGR	LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
INGR	DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	
INGR	TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
INGR	Denatonium Benzoate (UNII: 4YK5Z54AT2)	
INGR	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		12/01/2016	

Part 2 of 3

ZO MEDICAL RETINOL CREME COMPLEX

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

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Water (UNII: 059QF0KO0R)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	Polysorbate 20 (UNII: 7T1F30V5YH)	
INGR	Retinol (UNII: G2SH0XKK91)	
INGR	Glycerin (UNII: PDC6A3C0OX)	
INGR	ALLYL METHACRYLATE (UNII: G2IG50653Z)	
INGR	Stearyl Alcohol (UNII: 2KR89I4H1Y)	
INGR	Polysorbate 60 (UNII: CAL22UVI4M)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	Butylene Glycol (UNII: 3XUS85K0RA)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
INGR	Palmitic Acid (UNII: 2V16EO95H1)	
INGR	UBIDECARENONE (UNII: EJ27X76M46)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	Hydrogenated Jojoba Oil (UNII: 7F674YQ5SO)	
INGR	GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
INGR	Dimethicone (UNII: 92RU3N3Y1O)	
INGR	CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	Stearic Acid (UNII: 4ELV7Z65AP)	
INGR	LEVOMENOL (UNII: 24WE03BX2T)	
INGR	Ascorbic Acid (UNII: PQ6CK8PD0R)	
INGR	Sorbitol (UNII: 506T60A25R)	
INGR	Phenoxyethanol (UNII: HIE492ZZ3T)	
INGR	HEXAMETHYLCYCLOTRISILOXANE (UNII: EPV75L8O0R)	
INGR	CYCLOMETHICONE 4 (UNII: CZ227117JE)	
INGR	CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
INGR	GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

INGR	SAFFLOWER OIL (UNII: 65UEH262IS)	
INGR	CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
INGR	Xanthan Gum (UNII: TTV12P4NEE)	
INGR	Hexylene Glycol (UNII: KEH0A3F75J)	
INGR	Ethylhexylglycerin (UNII: 147D247K3P)	
INGR	Caprylyl Glycol (UNII: 00YIU5438U)	
INGR	BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
INGR	DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
INGR	APPLE FRUIT OIL (UNII: 9NT987BA8)	
INGR	Myristic Acid (UNII: 0I3V7S25AW)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2.5 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		12/01/2016	

Part 3 of 3

REVITATROL EPIDERMAL REPAIR SKIN PROTECTANT

oatmeal lotion

Product Information

Item Code (Source)	NDC:42851-083
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Petrolatum (UNII: 4T6H12BN9U)	
Distearyldimonium Chloride (UNII: OM9573ZX3X)	
Isopropyl Palmitate (UNII: 8CRQ2TH63M)	

CYCLOMETHICONE 5 (UNII: 0THF5PC10R)
Cetyl Alcohol (UNII: 936JST6JCN)
SHEA BUTTER (UNII: K49155WL9Y)
Benzyl Alcohol (UNII: LKG8494WBH)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)
Benzalkonium Chloride (UNII: F5UM2KM3W7)
Butylene Glycol (UNII: 3XUS85K0RA)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
Pentylene Glycol (UNII: 50C1307PZG)
1,2-Hexanediol (UNII: TR046Y3K1G)
Sodium Chloride (UNII: 451W47IQ8X)
Alcohol (UNII: 3K9958V90M)
Isopropyl Alcohol (UNII: ND2M416302)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
Ascorbic Acid (UNII: PQ6CK8PD0R)
Dibenzyl Ether (UNII: 2O6CNO27RJ)
Tetrapeptide-21 (UNII: 179JUC43HU)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-083-56	58 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
OTC MONOGRAPH FINAL	part347	12/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	12/01/2016	

Labeler - ZO Skin Health, Inc. (826468527)

Establishment

Name	Address	ID/FEI	Business Operations
G.S. COSMECEUTICAL USA, INC.		017014734	MANUFACTURE(42851-190)

Establishment

Name	Address	ID/FEI	Business Operations
PakLab		790530976	MANUFACTURE(42851-190)