

**ZO SKIN HEALTH SKIN NORMALIZING SYSTEM WITH ROZATROL BOOSTER SERUM-
salicylic acid**

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 Skin Normalizing System with Rozatrol[®] Booster Serum

Drug Facts

Active Ingredient

Salicylic Acid 2.0%

Purpose

Acne Treatment

Uses

- For the management of acne.
- Penetrates pores to control acne blemishes.

Warnings

Flammable. Keep away from heat and open flame.

For external use only.

When using this product

- Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.

Stop use and ask a doctor if

- If skin irritation occurs or gets worse.

Keep out of reach of children.

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

Directions

- Clean the skin thoroughly before applying this product.
- Cover the entire affected area with a thin layer one to three times daily.
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Other Information

- Read the directions and warnings before use.
- Store at 15–30°C (59–89°F), away from direct sunlight.

Inactive Ingredients

Alcohol, Artemisia Vulgaris Extract, Butylene Glycol, Camellia Sinensis Leaf Extract, Crithmum Maritimum Extract, Fragrance, Glycolic Acid, Hamamelis Virginiana (Witch Hazel) Extract, Hordeum Vulgare Seed Extract, Mandelic Acid, Menthyl Lactate, Phenoxyethanol, Phellodendron Amureuse Extract, Plantago Lanceolata Leaf Extract, Pterocarpus Soyauxii Wood Extract, Rosa Canina Fruit Extract, Sodium Hydroxide, Spiraea Ulmaria Extract, Urea, Water.

Dist. by ZO Skin Health, Inc.

5 Technology Dr. Irvine, CA 92618 | 910700

PRINCIPAL DISPLAY PANEL - Kit Carton

ZO[®] SKIN HEALTH

BY ZEIN OBAGI MD

SKIN NORMALIZING SYSTEM

WITH ROZATROL[®] BOOSTER SERUM

NDC 42851-186-60

DELIVERED BY

hydrafacial[®]



SKIN NORMALIZING SYSTEM
WITH ROZATROL® BOOSTER SERUM

ZO® SKIN HEALTH
BY ZEIN OBAGI MD



SKIN NORMALIZING SYSTEM
WITH ROZATROL® BOOSTER SERUM

NDC 42851-186-60

DELIVERED BY

hydracial®

210700

SKIN NORMALIZING SYSTEM

This skin normalizing system is a complete selection of products for red, sensitized skin. This system features Rozatrol®, a multi-modal treatment that normalizes skin by reducing excess surface oil and provides ultra-mild exfoliation to prevent the signs of premature aging.





IN-OFFICE TREATMENT

DELIVERED BY **hydracial**

Delivered by HydraFacial™ and powered by the science of ZO®, this booster serum is specifically designed to relieve the visible signs of red, sensitized skin.

HYDRAFACIAL ROZATROL® BOOSTER SERUM
US PATENT NO. 9,763,976
9 mL / 0.30 Fl. Oz.

DIRECTIONS Use only as directed. Insert vial into the cartridge handpiece. Make sure the vial snaps into place. Attach a new disposable HydroPeel® tip on the handpiece. Perform the treatment and then clean the handpiece after each service as instructed in your Service Protocol Manual.

WARNINGS For external use only. Avoid contact with eyes.

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

INGREDIENTS Aqua/Water/Eau, Glycerin, Butylene Glycol, Olive Oil PEG-8 Esters, Pentylene Glycol, Lactose, Propanediol, Rosa Canina Fruit Extract, Leontopodium Alpinum Meristem Cell Culture, Marrubium Vulgare Meristem Cell Culture, Lactis Proteinum/Milk Protein/Protéine du Lait, Papain, Tocopherol, Caprylyl Glycol, Hydrolyzed Algin, Sclerotium Gum, Xanthan Gum, Lecithin, Carbomer, Algin, Palmitoyl Glycine, PEG-12 Glyceryl Laurate, PEG-36 Castor Oil, Panthenyl Triacetate, 1,2-Hexanediol, Lactic Acid, Caprylhydroxamic Acid, Sodium Citrate, Farnesol, Farnesyl Acetate.

AT-HOME TREATMENT

STEP 1 GENTLE CLEANSER

60 mL / 2 Fl. Oz.

DIRECTIONS Massage a small amount on damp face and neck. Rinse thoroughly.

WARNINGS For external use only. Avoid contact with eyes. If contact occurs, rinse thoroughly with water. Keep out of reach of children.

INGREDIENTS Aqua/Water/Eau, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Lauroyl Sulfate, Glycerin, Pterocarpus Soyauxi Wood Extract, Phellodendron Amurense Bark Extract, Hordeum Distichon/Barley Extract/Extrait d'orge à deux rangs, Spiraea Ulmaria Leaf Extract, Camellia Sinensis Leaf Extract, Artemisia Vulgaris Extract, Plantago Lanceolata Leaf Extract, Crithmum Maritimum Extract, Fragrance (Parfum), Limonene, Linalool, Sodium Chloride, Butylene Glycol, Ethylhexylglycerin, Phenoxyethanol, Blue 1 (CI 42090), Red 33 (CI 17200).

STEP 2 EXFOLIATING POLISH

Net Wt. 16.2 g / 0.57 Oz.

DIRECTIONS Gently massage a small amount on damp face and neck. Rinse thoroughly.

WARNINGS For external use only. Avoid contact with eyes; if contact occurs, rinse thoroughly with water. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

INGREDIENTS PEG-8, Sodium Bicarbonate, Magnesium Oxide, Ethoxydiglycol, Glycerin, Butylene Glycol, Oleth-20, Trihydroxystearin, Glyceryl Stearate, PEG-100 Stearate, Paraffinum Liquidum/Mineral Oil/Huile minérale, Aqua/Water/Eau, Tocopheryl Acetate, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Glycine Soja (Soybean) Sterols, Fragrance (Parfum), Limonene, Linalool, Ascorbyl Palmitate, Refined Palmate, Stearyl Glycyrrhizinate, Tetrahydrodecyl Ascorbate, Caprylic/Capric Triglyceride, Linoleic Acid, Phospholipids, Phenoxyethanol, Green 6 (CI 61565).

STEP 3 OIL CONTROL PADS

ACNETREATMENT

60 Pads

Drug Facts

Active Ingredient	Purpose
Salicylic Acid 2.0%	Acne Treatment

Uses

- For the management of a acne.
- Penetrates pores to control acne blemishes.

Warnings

Flammable. Keep a way from heat and open flame. For external use only.

When using this product

- Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.

Stop use and ask a doctor if

- If skin irritation occurs or gets worse.

Keep out of reach of children.

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



Drug Facts (continued)

Directions

- Clean the skin thoroughly before applying this product.
- Cover the entire affected area with a thin layer one to three times daily.
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Other Information

- Read the directions and warnings before use.
- Store at 15–30°C (59–89°F), away from direct sunlight.

Inactive Ingredients

Alcohol, Artemisia Vulgaris Extract, Butylene Glycol, Camellia Sinensis Leaf Extract, Crithmum Maritimum Extract, Fragrance, Glycolic Acid, Hamamelis Virginiana (Witch Hazel) Extract, Hordeum Vulgare Seed Extract, Mandelic Acid, Menthyl Lactate, Phenoxyethanol, Phellodendron Amurense Extract, Plantago Lanceolata Leaf Extract, Pterocarpus Soyauxi Wood Extract, Rosa Canina Fruit Extract, Sodium Hydroxide, Spiraea Ulmaria Extract, Urea, Water.

STEP 5 ROZATROL®

US PATENT NO. 9,763,976

20 mL / 0.67 Fl. Oz.

DIRECTIONS Apply to clean, dry skin.

WARNINGS For external use only. If any adverse reaction occurs, stop using the product. Inform your physician if your condition persists. Avoid contact with eyes. If contact occurs, rinse thoroughly with cool water. Keep out of reach of children.

INGREDIENTS Aqua/Water/Eau, Glycerin, Cetyl Alcohol, Helianthus Annuus (Sunflower) Seed Oil, C12-15 Alkyl Benzoate, Palmitoyl Glycine, Neopentyl Glycol Diethylhexanoate, Dimethicone, Panthenol, Glyceryl Stearate, PEG-100 Stearate, Potassium Cetyl Phosphate, Lactose, Brassica Oleracea Italica (Broccoli) Extract, Lactis Proteinum/Milk Protein/Protéine du Lait, Leontopodium Alpinum Meristem Cell Culture, Marrubium Vulgare Meristem Cell Culture, Neopentyl Glycol Diisostearate, Papain, Magnesium Aluminum Silicate, PEG-12 Glyceryl Laurate, PEG-36 Castor Oil, Panthenyl Triacetate, Farnesol, Farnesyl Acetate, Aminomethyl Propanol, Caprylyl Glycol, Hydrolyzed Algin, Disodium EDTA, 1,2-Hexanediol, Carbomer, Lecithin, Algin, Xanthan Gum, Benzalkonium Chloride, Chlorphenesin, Phenoxyethanol.

SUNBURN ALERT FOR OIL CONTROL PADS & ROZATROL®

These products contain 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 these products and for a week afterwards.

STEP 4 DAILY POWER DEFENSE

30 mL / 1 Fl. Oz.

DIRECTIONS Apply to clean, dry skin.

WARNINGS For external use only. Avoid contact with eyes; if contact occurs, rinse thoroughly with water. Keep out of reach of children.

INGREDIENTS Aqua/Water/Eau, Cetearyl Isononanoate, Cyclopentasiloxane, Glycerin, Cyclohexasiloxane, Pentylene Glycol, Cetearyl Alcohol, Steareth-20, Jojoba Esters, C14-22 Alcohols, Cetearyl Glucoside, Safflower Oil/Palm Oil Aminopropanediol Esters, C12-20 Alkyl Glucoside, Carbomer, Lactose, Cellulose, Lecithin, Retinol, Beta-Glucan, 1,2-Hexanediol, Hydroxypropyl Methylcellulose, Micrococcus Lysate, Arabidopsis Thaliana Extract, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Nobilis (Mandarin Orange) Peel Oil, Citrus Reticulata (Tangerine) Peel Oil, Citrus Limon (Lemon) Peel Oil, Mentha Piperita (Peppermint) Oil, Mimosa Tenuiflora Bark Extract, Citrus Reticulata (Tangerine) Fruit Extract, Polysorbate 20, Farnesol, Limonene, Disodium EDTA, Sodium Hydroxide, Palmitoyl Tripeptide-1, Palmitoyl Tetrapeptide-7, Retinyl Palmitate, Tocopheryl Acetate, Caprylyl Glycol, Butylene Glycol, Hexylene Glycol, Ethylhexylglycerin, Phenoxyethanol, Ultramarines (CI 77007), Ext. Violet 2 (CI 60730).



Made in USA with US & imported materials

Dist. by ZO Skin Health, Inc.
5 Technology Dr. Irvine, CA 92618 | 910700

Edge Systems LLC
2277 Redondo Ave. Signal Hill, CA 90755
800.603.4996 | hydrafacial.com

ZO SKIN HEALTH SKIN NORMALIZING SYSTEM WITH ROZATROL BOOSTER SERUM

salicylic acid kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42851-186
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-186-60	1 in 1 CARTON	05/01/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL, GLASS	9 mL
Part 2	1 TUBE	60 mL
Part 3	1 JAR	16.2 g
Part 4	60 PATCH	48 mL
Part 5	1 BOTTLE	30 mL
Part 6	1 TUBE	20 mL

Part 1 of 6

ZO SKIN HEALTH HYDRAFACIAL ROZATROL BOOSTER SERUM

lotions, oils, powders, and creams lotion

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	PENTYLENE GLYCOL (UNII: 50C1307PZG)	
INGR	LACTOSE (UNII: J2B2A4N98G)	
INGR	PROPANEDIOL (UNII: 5965N8W85T)	
INGR	ROSA CANINA FRUIT (UNII: 3TNW8D08V3)	
INGR	CASEIN (UNII: 48268V50D5)	
INGR	PAPAIN (UNII: A236A06Y32)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	BETASIZOFIRAN (UNII: 2X51AD1X3T)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
INGR	CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
INGR	SODIUM ALGINATE (UNII: C269C4G2ZQ)	
INGR	PALMITOYL GLYCINE (UNII: M6V3RIU5KI)	
INGR	PEG-12 GLYCERYL LAURATE (UNII: J07WW42G15)	
INGR	POLYOXYL 35 CASTOR OIL (UNII: 6D4M1DAL6O)	
INGR	PANTHENOL TRIACETATE, (+)- (UNII: 1206E8961B)	
INGR	1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
INGR	LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
INGR	CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
INGR	SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
INGR	FARNESOL (UNII: EB41QIU6JL)	
INGR	FARNESYL ACETATE (UNII: 2ARF3ZNJ1R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		9 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		05/01/2018	

Part 2 of 6

ZO SKIN HEALTH GENTLE 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 LAURETH-3 SULFATE (UNII: BPV390UAP0)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	SODIUM LAUROYL OAT AMINO ACIDS (UNII: FSW2K9B9N5)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	PTEROCARPUS SOYAUXII WOOD (UNII: 0V6QB4C61P)	
INGR	PHELLODENDRON AMURENSE BARK (UNII: PBG27B754G)	
INGR	BARLEY (UNII: 5PWM7YLI7R)	
INGR	GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
INGR	PLANTAGO LANCEOLATA LEAF (UNII: 2YWL9J7EE8)	
INGR	CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
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		05/01/2018	

Part 3 of 6

ZO SKIN HEALTH EXFOLIATING POLISH

lotions, oils, powders, and creams 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	MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
INGR	DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	
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: 059QF0K00R)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	TEA TREE OIL (UNII: VIF565UC2G)	
INGR	SOY STEROL (UNII: PL360EPO9J)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
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		05/01/2018	

Part 4 of 6

ZO SKIN HEALTH OIL CONTROL PADS, ACNE TREATMENT

salicylic acid patch

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)	
BARLEY (UNII: 5PWM7YLI7R)	
MANDELIC ACID (UNII: NH496X0UJX)	
MENTHYL LACTATE, (-) (UNII: 2BF9E65L7I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PLANTAGO LANCEOLATA LEAF (UNII: 2YWL9J7EE8)	
PTEROCARPUS SOYAUXII WOOD (UNII: 0V6QB4C61P)	
ROSA CANINA FRUIT (UNII: 3TNW8D08V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
UREA (UNII: 8W8T17847W)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		60 in 1 JAR		
1		0.8 mL in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	05/01/2018	

Part 5 of 6

ZO SKIN HEALTH DAILY POWER DEFENSE

lotions, oils, powders, and creams lotion

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
INGR	PENTYLENE GLYCOL (UNII: 50C1307PZG)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	STEARETH-20 (UNII: L0Q8IK9E08)	
INGR	C14-22 ALCOHOLS (UNII: B1K89384RJ)	
INGR	CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
INGR	SAFFLOWER OIL (UNII: 65UEH262IS)	
INGR	C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	
INGR	CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
INGR	LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
INGR	POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
INGR	RETINOL (UNII: G2SH0XKK91)	
INGR	1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
INGR	HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
INGR	ARABIDOPSIS THALIANA (UNII: A13L60HQ81)	
INGR	ORANGE OIL (UNII: AKN3KSD11B)	
INGR	MANDARIN OIL (UNII: NJO720F72R)	
INGR	LEMON OIL (UNII: I9GRO824LL)	
INGR	PEPPERMINT OIL (UNII: AV092KU4JH)	
INGR	MIMOSA TENUIFLORA BARK (UNII: 515MQE449I)	
INGR	TANGERINE (UNII: KH3E3096OO)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	FARNESOL (UNII: EB41QIU6JL)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
INGR	PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
INGR	VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	PHENOXYETHANOL (UNII: HE492ZZ3T)	
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; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		05/01/2018	

Part 6 of 6

ZO SKIN HEALTH ROZATROL TREATMENT FOR RED, SENSITIZED SKIN

lotions, oils, powders, and creams lotion

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	SUNFLOWER OIL (UNII: 3W1JG795YI)	
INGR	ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
INGR	PALMITOYL GLYCINE (UNII: M6V3RIU5KI)	
INGR	NEOPENTYL GLYCOL DIETHYLHEXANOATE (UNII: U68ZV6W62C)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	PANTHENOL (UNII: WV9CM0O67Z)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	PEG-100 STEARATE (UNII: YD01N1999R)	
INGR	POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
INGR	LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
INGR	CASEIN (UNII: 48268V50D5)	
INGR	NEOPENTYL GLYCOL DIISO STEARATE (UNII: 4M6OQ34JWW)	
INGR	PAPAIN (UNII: A236A06Y32)	
INGR	MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
INGR	PEG-12 GLYCERYL LAURATE (UNII: J07WW42G15)	

INGR	POLYOXYL 35 CASTOR OIL (UNII: 6D4MIDAL6O)	
INGR	PANTHENOL TRIACETATE, (+)- (UNII: 1206E8961B)	
INGR	FARNESOL (UNII: EB41QIU6JL)	
INGR	FARNESYL ACETATE (UNII: 2ARF3ZNJ1R)	
INGR	AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
INGR	CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
INGR	SODIUM ALGINATE (UNII: C269C4G2ZQ)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
INGR	CHLORPHENESIN (UNII: I670DAL4SZ)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		20 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		05/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	05/01/2018	

Labeler - ZO Skin Health, Inc. (826468527)

Establishment

Name	Address	ID/FEI	Business Operations
Lifetech Resources, LLC		081239587	manufacture(42851-186)

Establishment

Name	Address	ID/FEI	Business Operations
Thibiant International, Inc.		083913913	manufacture(42851-186)

Establishment

Name	Address	ID/FEI	Business Operations
PakLab		790530976	manufacture(42851-186)

