

ZO SKIN HEALTH ACNE PREVENTION PLUS TREATMENT PROGRAM- sulfur
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 Acne Prevention + Treatment Program (NDC 42851-175-85)

Exfoliating Cleanser 200 mL

Exfoliating Polish 65 g

Complexion Renewal Pads 60 ct

Sulfur Masque (85 g) NDC 42851-089-85 NPN 80061274

SULFUR MASQUE Acne Treatment

Drug Facts

Active ingredients

Sulfur 10%

Purpose

Acne Treatment

Uses

For the treatment of acne. Penetrates pores to clear most acne blemishes, blackheads and whiteheads. Helps prevent new acne blemishes from forming.

Warnings

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.
- Apply only to areas with acne.

Do Not Use On

- Broken skin
- Large areas of skin.

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 twice a week.
- Leave on for 10-15 minutes and remove thoroughly with warm water, moist towels or cotton pads.
- if bothersome dryness or peeling occurs, reduce application frequency as directed by your doctor.
- As a spot treatment: apply a small amount onto the blemish and leave on overnight.

ZO SKIN HEALTH ACNE PREVENTION PLUS TREATMENT PROGRAM

sulfur kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42851-175
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-175-85	1 in 1 CARTON	01/17/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	200 mL
Part 2	1 JAR	65 g
Part 3	1 BOTTLE, GLASS	60
Part 4	1 TUBE	85 g

Part 1 of 4

ZO SKIN HEALTH EXFOLIATING CLEANSER

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	HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	COCAMIDOPROPYL HYDROXYSULTAINE (UNII: 62V75NI93W)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	MANNITOL (UNII: 3OWL53L36A)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)	
INGR	CAPRYLIC ALCOHOL (UNII: NV1779205D)	
INGR	POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	

INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	NIACINAMIDE (UNII: 25X518RD4)	
INGR	BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
INGR	AMMONIUM LACTATE (UNII: 67M901L9NQ)	
INGR	NIACIN (UNII: 2679MF687A)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	SALICYLIC ACID (UNII: O414PZ4LPZ)	
INGR	BIO SACCHARIDE GUM-1 (UNII: BB4PU4V09H)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	LINALOOL, (+/-)- (UNII: D81QY6I88E)	
INGR	CHROMIUM HYDROXIDE GREEN (UNII: RV8FT8XF5R)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		200 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		01/17/2019	

Part 2 of 4

ZO SKIN HEALTH EXFOLIATING POLISH

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

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
INGR	MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	OLETH-20 (UNII: YTH167I2AG)	
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	LINOLEIC ACID (UNII: 9KJL21T0QJ)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	LINALOOL, (+/-)- (UNII: D81QY6I88E)	
INGR	D&C GREEN NO. 6 (UNII: 4QP5U84YF7)	
INGR	POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	MINERAL OIL (UNII: T5L8T28FGP)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	SOY STEROL (UNII: PL360EPO9J)	
INGR	DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A18X02B)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		65 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		01/17/2019	

Part 3 of 4

ZO SKIN HEALTH COMPLEXION RENEWAL PADS

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

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	LINALOOL, (+/-)- (UNII: D81QY6I88E)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
INGR	UREA (UNII: 8W8T17847W)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	GLYCOLIC ACID (UNII: 0WT12SX38S)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	PTEROCARPUS SOYAUXII WOOD (UNII: 0V6QB4C61P)	

INGR	PLANTAGO LANCEOLATA LEAF (UNII: 2YWL9J7EE8)	
INGR	PHELLODENDRON AMURENSE BARK (UNII: PBG27B754G)	
INGR	BARLEY (UNII: 5PWM7YLI7R)	
INGR	CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
INGR	ARTEMISIA VULGARIS ROOT (UNII: 32MP823R8S)	
INGR	SALICYLIC ACID (UNII: O414PZ4LPZ)	
INGR	ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
INGR	.ALPHA.-HEXYL CINNAMALDEHYDE (UNII: 7X6O37OK2I)	
INGR	GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		60 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/17/2019	

Part 4 of 4

ZO SKIN HEALTH SULFUR MASQUE

sulfur cream

Product Information

Item Code (Source)	NDC:42851-089
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
TALC (UNII: 7SEV7J4R1U)	
KAOLIN (UNII: 24H4NWX5CO)	
GLYCERIN (UNII: PDC6A3C0OX)	
BENTONITE (UNII: A3N5ZCN45C)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)	

CHLORPHENESIN (UNII: I670DAL4SZ)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
EDETATE SODIUM (UNII: MP1J8420LU)	
ULTRAMARINE BLUE (UNII: I39WR998BI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		85 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	part333D	01/17/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/17/2019	

Labeler - ZO Skin Health, Inc. (826468527)

Establishment

Name	Address	ID/FEI	Business Operations
G.S. COSMECEUTICAL USA, INC.		017014734	manufacture(42851-175)

Establishment

Name	Address	ID/FEI	Business Operations
Lifetech Resources, LLC.		081239587	manufacture(42851-175)