

ZO SKIN HEALTH POST PROCEDURE RECOVERY SYSTEM- aluminum acetate
ZO Skin Health, Inc.

ZO ® Skin Health Post Procedure Recovery System

Drug Facts

| <i>Active Ingredient</i> | <i>Purpose</i> |
|---|-----------------------|
| Aluminum Sulfate Tetradecahydrate, 2850 mg | Astringent * |
| Calcium Acetate Monohydrate, 2016 mg | Astringent * |

* When combined together in water, these ingredients form the active ingredient aluminum acetate. See Directions

Uses

- For temporary relief of minor skin irritations due to rashes caused by soaps, detergents, cosmetics, or jewelry.

Warnings

For external use only.

When using this product

- avoid contact with eyes. If contact occurs, rinse thoroughly with water.
- do not cover compress or wet dressing with plastic to prevent evaporation
- in some skin conditions, soaking too long may overdry

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days

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

Directions

- dissolve 1 packet in 12 oz. of cool or warm water.
- stir until fully dissolved; do not strain or filter.

The resulting mixture contains 0.45% aluminum acetate and is ready for use.

For use as a compress or wet dressing:

- soak a clean, soft cloth in the solution
- apply cloth loosely to affected area for 15 to 30 minutes
- repeat as needed or as directed by a doctor
- discard solution after each use

Inactive Ingredients

Water, Dextrin, Avena Sativa (Oat) Kernel Protein, Glycine Soja (Soybean) Protein, Whey Protein, Potassium Sorbate, Chitosan.

Other Information

- Store at controlled room temperature: 15-30°C (59-86°F), away from direct sunlight.
- You may report a serious adverse reaction to: 5 Technology Dr. Irvine, CA 92618

Dist. by ZO Skin Health, Inc. Irvine, CA 92618

PRINCIPAL DISPLAY PANEL - Kit Carton

ZO[®] SKIN HEALTH
BY ZEIN OBAGI MD

POST PROCEDURE RECOVERY SYSTEM

NDC 42851-193-06

POMATROL[®] Soothing Ointment 50 mL / 1.7 Fl. Oz.

HYDRATING CRÈME Net Wt. 113 g / 4 Oz.

SURFATROL[®] Astringent Solution Powder 10 ea. Net Wt. 6 g / 0.21 Oz.

US Patent No. 9,248,160



POST PROCEDURE RECOVERY SYSTEM

ZO[®] SKIN HEALTH
by ZEIN OBAĞI MD

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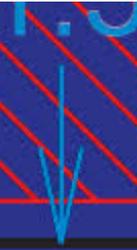


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US Patent No. 9,248,160





POMATROL® Soothing Ointment

50 mL / 1.7 Fl. Oz.

DIRECTIONS Use for the first four days post-procedure. After gently cleansing affected area and/or after applying Surfamol®, an astringent solution compress, apply a thin coat of ointment and gently massage onto skin to protect and keep out airborne dirt and debris. This helps suppress dryness and scabbing. Applying too much ointment can cause premature skin peeling and increase the likelihood of post-procedure acne. Can also be used whenever skin feels dry or uncomfortable.

CAUTION For external use only. Use only as directed. Keep out of eyes. If contact occurs, rinse thoroughly with cool water. Keep out of reach of children. If rash or other adverse reaction occurs, discontinue use and contact your doctor.

INGREDIENTS Water, Hydrogenated Polyisobutene, Caprylic/Capric/Myristic/Stearic Triglyceride, Glycerin, Tribehenin, PEG-15/Lauryl Dimethicone Crosspolymer, Helianthus Annuus (Sunflower) Seed Oil, Beta-Glucan, Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Triethylhexanoin, Polymethyl Methacrylate, Phenoxyethanol, Magnesium Sulfate, Hexyl Laurate, Brassica Oleracea Italica (Broccoli) Extract, Avena Sativa (Oat) Kernel Flour, Panthenyl Triacetate, Fragrance, Ethyl Linoleate, Erythritol, Chlorphenesin, C12-15 Alkyl Benzoate, Tocopheryl Acetate, Oleyl Alcohol, Butylene Glycol, Acetyl Tyrosine, Aminopropyl Dihydrogen Phosphate, Proline, Ubiquinone, Retinyl Palmitate, Ascorbic Acid, Tocopherol, Hydrolyzed Vegetable Protein, Adenosine Triphosphate, Disodium Acetyl Glucosamine Phosphate, Sodium Hyaluronate, Sodium Benzoate, Potassium Sorbate, PEG-35 Castor Oil, PEG-12 Glyceryl Laurate, Homarine HCL, PVP, Disodium EDTA.

HYDRATING CRÈME

Net Wt. 113 g / 4 Oz.

DIRECTIONS Apply to clean, dry skin as needed.

WARNINGS For external use only. Avoid contact with

Drug Facts (continued)

ingredients form the active ingredient aluminum acetate. See **Directions**

Uses

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Directions

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- stir until fully dissolved; do not strain or filter. The resulting mixture contains 0.45% aluminum acetate and is ready for use.

For use as a compress or wet dressing:

- soak a clean, soft cloth in the solution
- apply cloth loosely to affected area for 15 to 30

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, Glycerin, Petrolatum, Distearyl dimonium Chloride, Isopropyl Palmitate, Cyclopentasiloxane, Cetyl Alcohol, Butyrospermum Parkii (Shea) Butter, Colloidal Oatmeal, Ophiopogon Japonicus Root Extract, Tocopheryl Acetate, Retinyl Palmitate, Ascorbic Acid, Beta-Glucan, Tetrapeptide-21, Myristoyl Pentapeptide-11, Polymethyl Methacrylate, Dipotassium Glycyrrhizate, Maltodextrin, Benzalkonium Chloride, Butylene Glycol, Sodium Chloride, Benzyl Alcohol.

SURFATROL® Astringent Solution Powder
10 ea. Net Wt. 6 g / 0.21 Oz. (NDC 42851-088-06)

Drug Facts

| Active Ingredient | Purpose |
|--|-------------|
| Aluminum Sulfate | |
| Tetradecahydrate, 2850 mg | Astringent* |
| Calcium Acetate Monohydrate, 2016 mg | Astringent* |

*When combined together in water, these

- apply cloth loosely to affected area for 15 to 30 minutes
- repeat as needed or as directed by a doctor
- discard solution after each use

Inactive Ingredients

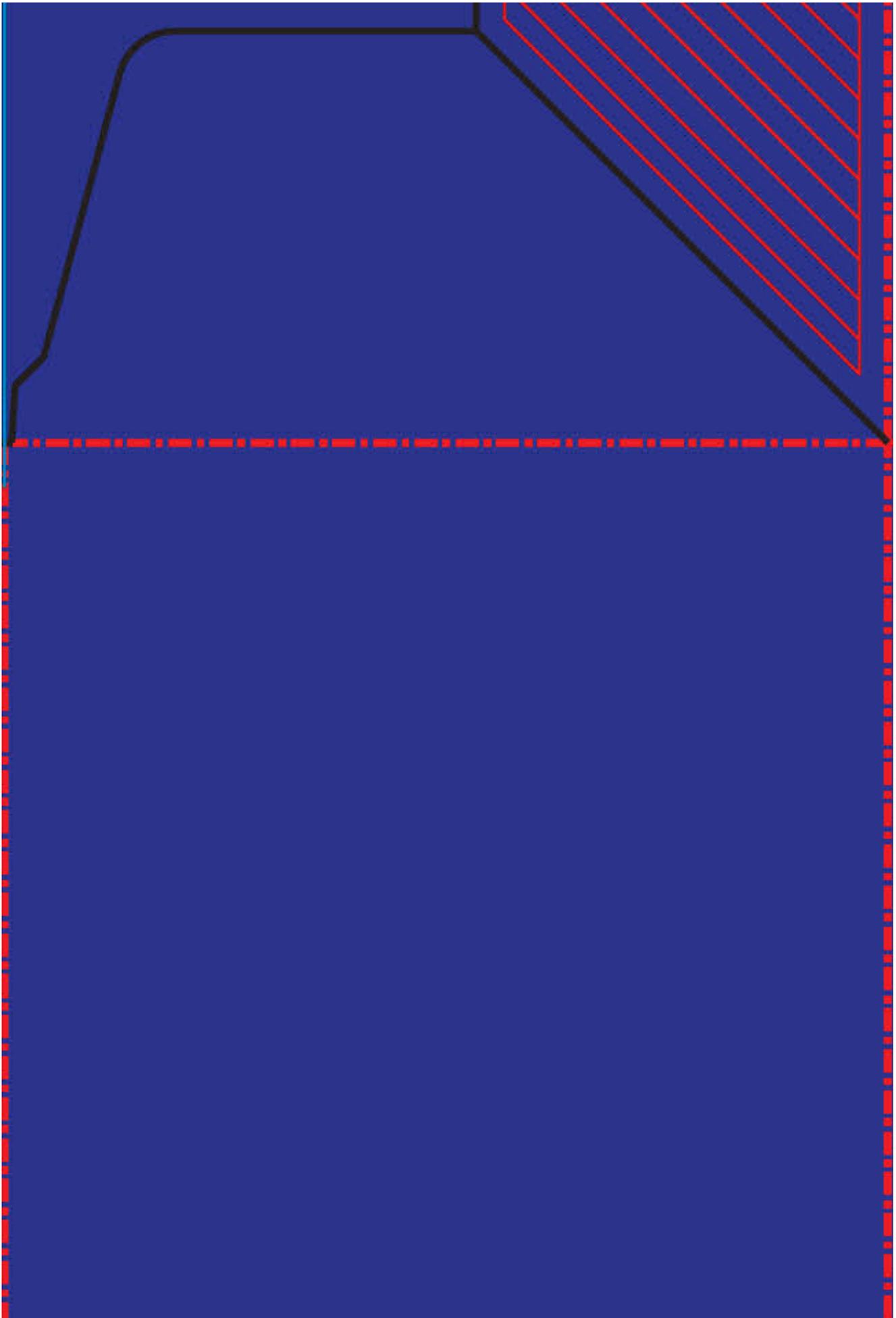
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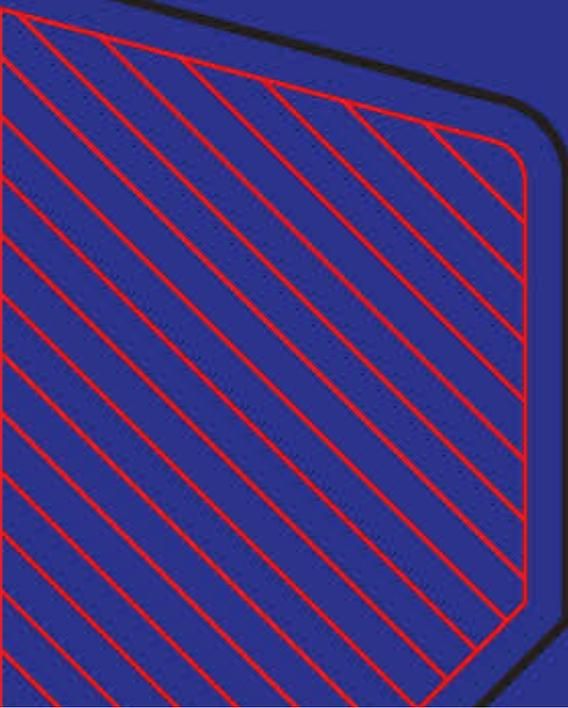
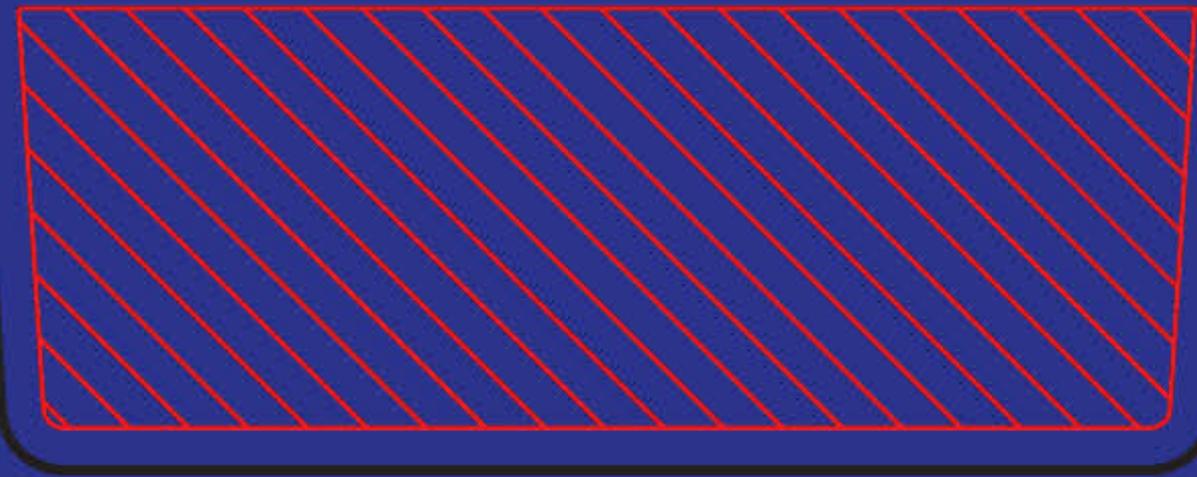
Other Information

- Store at controlled room temperature: 15-30°C (59-86°F), away from direct sunlight.
- You may report a serious adverse reaction to: 5 Technology Dr. Irvine, CA 92618

NOTE: See insert for Post Procedure Recovery System regimen instructions

Dist. by ZO Skin Health, Inc. Irvine, CA 92618
Made in USA with US & imported material
zoskinhealth.com | 914500







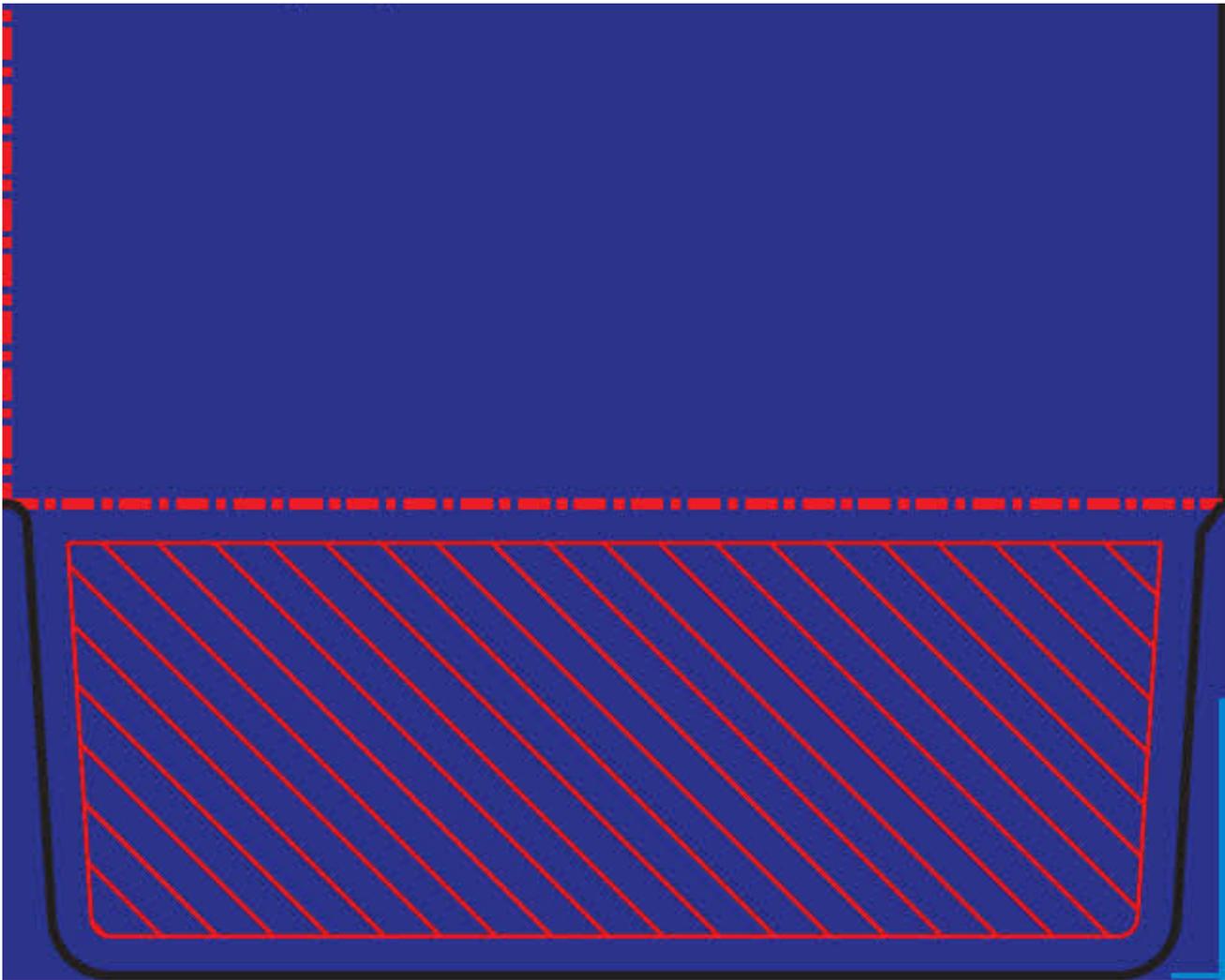
POST PROCEDURE RECOVERY SYSTEM

The Post Procedure Recovery System, developed by Zein Obagi MD, is the most effective program for post procedure skin management. This post procedure recovery system is designed for use after laser resurfacing procedures, chemical peels or any combined ablative treatment. The three products are formulated to synergistically deliver the most advanced technology available to protect and soothe skin while natural re-epithelialization of the skin is completed.

POMATROL® Soothing Ointment: A semi occlusive ointment that will keep skin moist and keep out airborne dirt and debris, providing an environment for skin recovery to begin.

HYDRATING CRÈME: Delivers hydrating and calming benefits for post-procedure or dry and irritated skin. Formula rejuvenates skin renewal while improving appearance of fine lines and wrinkles.

SURFATROL® Astringent Solution Powder: Soothing, effective solution that when mixed with water and applied to skin, provides ultimate skin relief to calm irritation, which is important in helping to prevent scabbing and to guard against other normal post procedure reactions.



ZO SKIN HEALTH POST PROCEDURE RECOVERY SYSTEM

aluminum acetate kit

Product Information

| | | | |
|---------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:42851-193 |
|---------------------|----------------|---------------------------|---------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:42851-193-06 | 1 in 1 CARTON | 01/31/2019 | |

Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|---------------|------------------|------------------------|
| Part 1 | 1 TUBE | 50 mL |
| Part 2 | 1 TUBE | 113 g |
| Part 3 | 1 PACKET | 6 g |

Part 1 of 3

ZO SKIN HEALTH POMATROL SOOTHING

cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] ointment

Product Information

Route of Administration TOPICAL

Other Ingredients

| Ingredient Kind | Ingredient Name | Quantity |
|-----------------|---|----------|
| INGR | WATER (UNII: 059QF0K00R) | |
| INGR | HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ) | |
| INGR | GLYCERIN (UNII: PDC6A3C00X) | |
| INGR | TRIBEHENIN (UNII: 8OC9U7TQZ0) | |
| INGR | SUNFLOWER OIL (UNII: 3W1JG795YI) | |
| INGR | POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7) | |
| INGR | TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K) | |
| INGR | POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11) | |
| INGR | PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| INGR | MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB) | |
| INGR | HEXYL LAURATE (UNII: 4CG9F9W01Q) | |
| INGR | BROCCOLI (UNII: UOI4FT57BZ) | |
| INGR | OATMEAL (UNII: 8PI54V663Y) | |
| INGR | PANTHENOL TRIACETATE, (+)- (UNII: 1206E8961B) | |
| INGR | ETHYL LINOLEATE (UNII: MJ2YTT4J8M) | |
| INGR | ERYTHRITOL (UNII: RA96B954X6) | |
| INGR | CHLORPHENESIN (UNII: I670DAL4SZ) | |
| INGR | ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| INGR | .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| INGR | OLEYL ALCOHOL (UNII: 172F2WN8DV) | |
| INGR | BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| INGR | N-ACETYLTYSOSINE (UNII: DA8G610ZO5) | |
| INGR | AMINOPROPYL DIHYDROGEN PHOSPHATE (UNII: D5J0Q2CM4V) | |
| INGR | PROLINE (UNII: 9DLQ4CIU6V) | |
| INGR | UBIDECARENONE (UNII: EJ27X76M46) | |
| INGR | VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) | |
| INGR | ASCORBIC ACID (UNII: PQ6CK8PD0R) | |
| INGR | TOCOPHEROL (UNII: R0ZB2556P8) | |
| INGR | ADENOSINE TRIPHOSPHATE (UNII: 8L70Q75FXE) | |
| INGR | DISODIUM ACETYL GLUCOSAMINE PHOSPHATE (UNII: SC89MF712W) | |
| INGR | HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| INGR | SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| INGR | POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| INGR | POLYOXYL 35 CASTOR OIL (UNII: 6D4M1DAL6O) | |
| INGR | PEG-12 GLYCERYL LAURATE (UNII: J07WW42G15) | |
| INGR | HOMARINE HYDROCHLORIDE (UNII: 8866LNG61N) | |

| | | |
|------|--|--|
| INGR | POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| INGR | EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 | | 50 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 | | 01/31/2019 | |

Part 2 of 3

ZO SKIN HEALTH HYDRATING CREME

body and hand (excluding shaving preparations), rinse-off [skin care preparations (creams, lotions, powder, and sprays)] lotion

Product Information

Route of Administration TOPICAL

Other Ingredients

| Ingredient Kind | Ingredient Name | Quantity |
|-----------------|--|----------|
| INGR | WATER (UNII: 059QF0KO0R) | |
| INGR | GLYCERIN (UNII: PDC6A3C0OX) | |
| INGR | PETROLATUM (UNII: 4T6H12BN9U) | |
| INGR | DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X) | |
| INGR | ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M) | |
| INGR | CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) | |
| INGR | CETYL ALCOHOL (UNII: 936JST6JCN) | |
| INGR | SHEA BUTTER (UNII: K49155WL9Y) | |
| INGR | OATMEAL (UNII: 8PI54V663Y) | |
| INGR | OPHIOPOGON JAPONICUS ROOT (UNII: 90PS6JV9GZ) | |
| INGR | .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| INGR | VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) | |
| INGR | ASCORBIC ACID (UNII: PQ6CK8PD0R) | |
| INGR | TETRAPEPTIDE-21 (UNII: 179JUC43HU) | |
| INGR | MYRISTOYL PENTAPEPTIDE-4 (UNII: PMA59A699X) | |
| INGR | POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11) | |
| INGR | GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX) | |

| | | |
|------|---|--|
| INGR | MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| INGR | BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |
| INGR | BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| INGR | SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| INGR | BENZYL ALCOHOL (UNII: LKG8494WBH) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 | | 113 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 |
|--------------------|--|----------------------|--------------------|
| Cosmetic | | 01/31/2019 | |

Part 3 of 3

ZO SKIN HEALTH SURFATROL ASTRINGENT SOLUTION

aluminum acetate powder

Product Information

| | |
|--------------------------------|---------------|
| Item Code (Source) | NDC:42851-088 |
| Route of Administration | TOPICAL |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ALUMINUM ACETATE (UNII: 80EHD8I43D) (ALUMINUM CATION - UNII:3XHB1D032B) | ALUMINUM ACETATE | 4866 mg in 6 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| OAT (UNII: Z6J799EAJK) | |
| SOY PROTEIN (UNII: R44IWB3RN5) | |
| WHEY (UNII: 8617Z5FMF6) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:42851-088-06 | 6 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 |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M016 | 01/31/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M016 | 01/31/2019 | |

Labeler - ZO Skin Health, Inc. (826468527)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|------------------------|
| Bentley Laboratories, LLC | | 068351753 | manufacture(42851-193) |

Revised: 12/2024

ZO Skin Health, Inc.