

ALUMIER MD INTENSIVE RECOVERY- hydrocortisone cream

Alumier Labs

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.

Alumier MD Intensive Recovery

Drug Facts

Active Ingredient

Hydrocortisone 1.0%

Purpose

Anti-itch cream

Uses

- adults and children 2 years of age and older: For the temporary relief of minor skin irritations, rashes, itching and redness due to eczema, insect bites, poison ivy, poison oak, poison sumac, contact dermatitis (e.g. caused by soaps, detergents, cosmetics and/or jewelry), seborrheic dermatitis, psoriasis.

Warnings

- **For external use only.**
- **do not use** for the treatment of diaper rash, except on the advice of a physician

When using this product

- avoid contact with eyes, do not use in or around the eyes

Stop use and ask a doctor if condition worsens or if symptoms persist for more than 7 days or clears up and occurs again within a few days. Do not begin use of any other hydrocortisone product unless directed by a physician.

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

Directions

- adults and children 2 years of age and older, apply sparingly to affected area not more than three to four times daily
- **do not use** on children under 2 years of age, consult a physician

Other Information

- Do not use if security seal is broken or missing.
- You may report a serious adverse reaction event from using this product to: Alumier Labs Inc., 550 Cochituate Road, Suite 25, Framingham, MA 01701

Inactive Ingredients

Water/Aqua/Eau, Propanediol, Butyrospermum Parkii (Shea Butter), Simmondsia Chinensis (Jojoba) Seed Oil, Glycerin, Dimethicone, Caprylic/Capric Triglyceride, Butylene Glycol, Behenyl Alcohol, Theobroma Cacao (Cocoa) Seed Butter, Sodium Acrylates Copolymer, Niacinamide, Aloe Barbadensis Leaf Juice, Hinokitiol, Resveratrol, Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, Anthemis Nobilis Flower Extract, Sea Whip Extract, Boswellia Serrata Extract, Honey Extract (Extrait de Miel), Tetrapeptide-14, Copper Tripeptide-1, Camellia Sinensis Leaf Extract, Aspalathus Linearis (Rooibos) Extract, Eucalyptus Globulus Leaf Extract, Mentha Viridis (Spearmint) Extract, Pogostemon Cablin Leaf Extract, Pyrus Malus (Apple) Fruit Extract, Rose Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Vaccinium Macrocarpon (Cranberry) Fruit Extract, Hydrogenated Lecithin, Squalane, Lecithin, Xanthan Gum, Caprylic Acid, Pentylene Glycol, Isosqualane, Sodium Methyl Stearoyl Taurate, Tricaprylin, Polymethyl Methacrylate, Sodium Hydroxide, Disodium EDTA, Caprylyl Glycol, Xylitol, Ethylhexylglycerin.

Company Information

Alumier MD

ALUMIER EUROPE LTD.

5 ST. FREDERICK STREET
VALLETTA VLT 1470, MALTA

WWW.ALUMIERMD.COM

EUROPE • UNITED STATES • CANADA
UNITED KINGDOM

DISTRIBUTED IN CANADA BY
ALUMIER LABS INC.,

436 LIMESTONE CRESCENT
TORONTO, ON, M3J 2S4

DISTRIBUTED IN THE USA BY
ALUMIER LABS INC.,

550 COCHITUATE ROAD, SUITE 25
FRAMINGHAM, MA 01701

MANUFACTURED IN CANADA UNDER

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DOCOSANOL (UNII: 9G1OE216XY)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
TRICAPRYLIN (UNII: 6P92858988)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
XYLITOL (UNII: VCQ006KQ1E)	
HONEY (UNII: Y9H1V576FH)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
MENTHA SPICATA (UNII: O2H83I4PUN)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
JOJOBA OIL (UNII: 724GKU717M)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
WATER (UNII: 059QF0KO0R)	
SHEA BUTTER (UNII: K49155WL9Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPANEDIOL (UNII: 5965N8W85T)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
NIACINAMIDE (UNII: 25X51I8RD4)	
.BETA.-THUJAPLICIN (UNII: U5335D6EBI)	
RESVERATROL (UNII: Q369O8926L)	
PREZATIDE COPPER (UNII: 6BJQ43T1I9)	
LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
APPLE (UNII: B423VGH5S9)	
ROSEMARY (UNII: IJ67X351P9)	
CRANBERRY (UNII: 0MVO31Q3QS)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ASPALATHUS LINEARIS WHOLE (UNII: O17JQA1A9Z)	
SQUALANE (UNII: GW89575KF9)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CAPRYLIC ACID (UNII: OBL58JN025)	
SODIUM METHYL STEAROYL TAURATE (UNII: JFM219LJ55)	

POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69473-017-01	1 in 1 CARTON	03/08/2022	
1		236 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 not final	part348	03/08/2022	

Labeler - Alumier Labs (079603173)

Revised: 3/2022

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