

SKIN PROTECTANT- colloidal oatmeal ointment
ELAJ, LLC

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.

SKIN PROTECTANT

Active Ingredient

Colloidal Oatmeal 1.0%

Purpose

Skin Protectant

Uses

Temporarily protects and helps relieve minor skin irritations and itching due to eczema

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 and occur again within a few days.

Keep out of reach of children

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

Directions

- Apply as needed or recommended 3-4 x a day initially during flare up and as needed after flareup begins to subside
- Apply generously before bed to help avoid itching while sleeping

Storage

Store at room temperature

Inactive Ingredients

USP White Petrolatum, Lemon Concentrate, Glycerin, Honey, Prunus Amygdalus Dulcis (Almond Oil), Alpha tocopherol (Vitamin E), Beeswax, Soy Wax, Talc, Boric acid, Zinc oxide, Stearic acid, Pistachia lenticus (Mastica), Vanilla

Questions or Comments

1-844-Buy-ELAJ (949-581-1200) or visit www.elajnaturally.com

Product Packaging Labels

<p>Why ELAJ™?</p> <ul style="list-style-type: none"> Your skin deserves the best quality ingredients available. Gentle enough for sensitive skin Can be used on face and lips as a deep, intensive moisturizer. Helps calm down flareups by reducing itching which promotes skin to <p>Let the <i>healing</i> begin...™</p> <p>Made exclusively for: ELAJ™, LLC Laguna Hills, CA, 92653 MADE IN USA www.elajnaturally.com</p>	<p>DRUG FACTS</p> <p>ACTIVE INGREDIENTS Colloidal Oatmeal 1.0%</p> <p>PURPOSE Skin Protectant</p> <p>USES Temporarily protects and helps relieve minor skin irritations and itching due to eczema.</p> <p>WARNINGS For external use only. Where 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 and occur again within a few days. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>DIRECTIONS • Apply as needed or recommended 3-4 x a day initially during flare up and as needed after flareup begins to subside. • Apply generously before bed to help avoid itching while sleeping. Other information: • Store at room temperature.</p> <p>Inactive Ingredients: ZSP White Petrolatum, Lemon Concentrate, Glycerin, Honey, Prunus Amygdalus Dulcis (Almond Oil), Alpha Tocopherol (Vitamin E), Beeswax, Soy Wax, Zinc, Boric acid, Zinc Oxide, Stearic acid, Pentaerythrityl Tetraethyl Sebacate.</p> <p>Questions or comments? 1-844-Buy-ELAJ (949-581-1200) or visit www.elajnaturally.com</p>	<p>ELAJ™ Promise</p> <p>Let the <i>healing</i> begin...™</p> <p>That is our mantra and comes before all else. Our obsession with the highest quality ingredients goes beyond standard manufacturing procedures and sourcing the best of the best.</p> <p>We offer a money-back guarantee for ELAJ™ products and if you are unsatisfied, please contact us for a full refund within 30 days of purchase with receipt.</p> <p>Congratulations! Your purchase contributes to our humanitarian mission of:</p> <p>Healing Scars Globally www.healingscarsglobally.org</p> <p>ELAJ™, LLC donates directly to victims of war and violence around the world!</p>	<p>Active Ingredient: 1% Colloidal Oatmeal</p> <p>NDC 69123-111-01</p> <p>ELAJ™</p> <p>Let the <i>healing</i> begin...™</p> <p>SKIN PROTECTANT Temporarily protects and helps relieve minor skin irritations and itching due to eczema.</p> <p>INTENSIVE MOISTURIZING OINTMENT ECZEMA THERAPY Made with Natural Ingredients Colloidal Oatmeal</p> <p>202 570M</p>
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57 g, 113 g, and 227 g Box Labels

<p>ELAJ™</p> <p>Let the <i>healing</i> begin...™</p> <p>202 570M</p>	<p>NDC 69123-111-01 Active Ingredient: 1% Colloidal Oatmeal</p> <p>SKIN PROTECTANT Temporarily protects and helps relieve minor skin irritations and itching due to eczema.</p> <p>INTENSIVE MOISTURIZING OINTMENT ECZEMA THERAPY</p> <p>Made exclusively for: ELAJ™, LLC Laguna Hills, CA, 92653 MADE IN USA www.elajnaturally.com</p> <p>PURPOSE Skin Protectant DIRECTIONS: • Apply as needed or recommended 3-4 x a day initially during flare up and as needed after flareup begins to subside. • Apply generously before bed to help avoid itching while sleeping. Questions or comments? 1-844-Buy-ELAJ (949-581-1200) Please Refer to Insert for Instructions or visit our website at www.elajnaturally.com</p>
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57 g, 113 g, and 227 g Container Labels

SKIN PROTECTANT

colloidal oatmeal ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69123-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	0.57 g in 57 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
GLYCERIN (UNII: PDC6A3C0OX)	
HONEY (UNII: Y9H1V576FH)	
ALMOND OIL (UNII: 66YXD4DKO9)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
Talc (UNII: 7SEV7J4R1U)	
BORIC ACID (UNII: R57ZHV85D4)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
Vanilla (UNII: Q74T35078H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69123-111-01	1 in 1 BOX		
1		57 g in 1 CONTAINER		
2	NDC:69123-111-02	1 in 1 BOX		
2		113 g in 1 CONTAINER		
3	NDC:69123-111-03	1 in 1 BOX		
3		227 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/25/2014	

Labeler - ELAJ, LLC (051975632)

Registrant - ELAJ, LLC (051975632)

