

**BABY ECZEMA RELIEF- calendula officinalis flower, sambucus nigra flower salve
PUREMEDY**

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

ACTIVE INGREDIENTS

ORG. CALENDULA OFFICINALIS (1X) HPUS) (MARIGOLD)

ORG. SAMBUCUS NIGRA (1X) HPUS (ELDER BARK AND FLOWER)

PURPOSE

SOOTHES RASH, IRRITATION

REMEDY FOR SWELLING

USES: TO RELIEVE SYMPTOMS ASSOCIATED WITH DIAPER RASH AND MINOR SKIN IRRITATIONS. SOOTHES SKINS AND PROTECTS AGAINST MOISTURE TP PROMOTE HEALING.

DIRECTIONS: APPLY TO CLEAN SKIN AFTER EACH DIAPER CHANGE OR AS DIRECTED BY YOUR PHYSICIAN. MAY ALSO BE USED AS A DAILY SKIN PROTECTANT.

INACTIVE INGREDIENTS: ORG. OLIVE OIL, ORG. BEESWAX, MILD PROPRIETARY BLEND OF PINE AND FIR EXTRACTS, ORG. COCOA BUTTER, ORG. MILK THISTLE, ORG. ST. JOHN'S WORT, ORG. ALOE VERA GEL, ORG. NON-GMO VITAMIN E

WARNINGS: DO NOT USE IF ALLERGIC TO OR SENSITIVE TO ANY INGREDIENT IN THIS SALVE. TEST FOR ALLERGY BY RUBBING A SMALL AMOUNT ON SKIN BEFORE USE. IF CONDITION PERSISTS OR WORSENS AFTER 3 DAYS SEE A DOCTOR. AVOID DIRECT CONTACT WITH EYES. USE ONLY AS DIRECTED. KEEP ALL DRUGS OUT OF USE OF CHILDREN. SAFE TO USE FOR ALL AGES.

KEEP ALL DRUGS OUT OF REACH OF CHILDREN.

STORE IN A COOL DRY PLACE OR REFRIGERATE.

CUSTOMER SERVICE 818-851-9014

<p>DRUG FACTS</p> <table border="0"> <tr> <th style="text-align: left;">ACTIVE INGREDIENTS</th> <th style="text-align: left;">PURPOSE</th> </tr> <tr> <td>Calendula Officinalis* (1X) HPUS (marigold).....</td> <td>skin healing agent</td> </tr> <tr> <td>Sambucus Nigra* (1X) HPUS (elderberry).....</td> <td>remedy for swelling</td> </tr> <tr> <td>Berberis Vulgaris* (1X) HPUS.....</td> <td>remedy for eczema</td> </tr> <tr> <td>Thuja Occidentalis* (1X) HPUS (arbor vitae).....</td> <td>remedy for eczema</td> </tr> </table> <p>Uses: To relieve symptoms associated with baby eczema, and as a skin protectant. Soothes and nourishes dry flaky skin.</p> <p>Directions: Apply topically as needed or as directed by your Physician.</p> <p>Inactive Ingredients: olive oil*, beeswax*, mild proprietary blend of pine and fir extracts**, cocoa butter*, vitamin e oil*, milk seed thistle*.</p> <p><small>* Certified Organic **Wild Harvested</small></p>	ACTIVE INGREDIENTS	PURPOSE	Calendula Officinalis* (1X) HPUS (marigold).....	skin healing agent	Sambucus Nigra* (1X) HPUS (elderberry).....	remedy for swelling	Berberis Vulgaris* (1X) HPUS.....	remedy for eczema	Thuja Occidentalis* (1X) HPUS (arbor vitae).....	remedy for eczema	 <p>nourishes • protects • gentle • petroleum free • 100% natural</p> <p>HOMEOPATHIC SALVE NDC #</p> <p>1 fl oz 30 ml</p>	<p style="color: orange;">Ancient Remedies for Modern People</p> <p>DRUG FACTS (continued)</p> <p>Warnings: Do not use if allergic to or sensitive to any ingredient in this salve. Test for allergy by rubbing a small amount on skin before use. If condition persists or worsens after 3 days see a doctor. Avoid direct contact with eyes. Use only as directed. Keep all drugs out of the reach of children. Safe to use for all ages.</p> <p>Store in a cool dry place.</p> <p>www.puremedy.com 31192 La Baya Dr. Ste. C Westlake Village, CA 91362 Customer Service: 818-851-9014</p>
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BABY ECZEMA RELIEF			
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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:528 10-217
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) (CALENDULA OFFICINALIS FLOWER - UNII:P0M7O4Y7YD)	CALENDULA OFFICINALIS FLOWER	1 [hp_X] in 100 mL
SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T) (SAMBUCUS NIGRA FLOWER - UNII:07V4DX094T)	SAMBUCUS NIGRA FLOWER	1 [hp_X] in 100 mL

Inactive Ingredients

Ingredient Name	Strength
OLIVE OIL (UNII: 6UYK2W1W1E)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CANADA BALSAM (UNII: K304VI98I3)	
COCOA BUTTER (UNII: 512OYT1CRR)	
SILYBUM MARIANUM SEED (UNII: U946SH95EE)	
ST. JOHN'S WORT (UNII: UFH8805FKA)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:528 10-217-11	30 mL in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/18/2012	

Labeler - PUREMEDY (003552251)**Establishment**

Name	Address	ID/FEI	Business Operations
COASTAL CONTRACT PACKAGING, INC.		137341611	manufacture(528 10-217)

Revised: 6/2015

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