

**BABY ACNE- calendula officinalis flower, sambucus nigra flower, thuja occidentalis 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.*

**BABY ACNE (52810-214)**

ACTIVE INGREDIENTS

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

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

ORG. THUJA OCCIDENTALIS (1X) HPUS (ARBOR VITAE)

PURPOSE

SKIN HEALING AGENT

REMEDY FOR SWELLING

REMEDY FOR ACNE

USES: TO RELIEVE SYMPTOMS ASSOCIATED WITH BABY ACNE.

DIRECTIONS: APPLY TOPICALLY AS NEEDED OR AS DIRECTED BY YOUR PHYSICIAN.

INACTIVE INGREDIENTS: ORG. OLIVE OIL, ORG. BEESWAX, ORG. COCOA BUTTER, MILD PROPRIETARY BLEND OF PINE AND FIR EXTRACTS

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

<b>DRUG FACTS</b>		<b>Ancient Remedies for Modern People</b>
<b>ACTIVE INGREDIENTS</b>	<b>PURPOSE</b>	<b>DRUG FACTS</b> (continued)
Calendula Officinalis* (1X) HPUS (marigold).....	skin healing agent	<b>Warnings: Do not use if allergic to or sensitive to any ingredient in this salve.</b>
Sambucus Nigra* (1X) HPUS (elderberry).....	remedy for swelling	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.
Thuja Occidentalis* (1X) HPUS (arbor vitae).....	remedy for acne	
<b>Uses:</b> To relieve symptoms associated with baby acne.		<b>Store in a cool dry place</b>
<b>Directions:</b> Apply topically as needed or as directed by your physician.		<b>www.puremedy.com</b>
<b>Inactive Ingredients:</b> olive oil*, beeswax*, cocoa butter*, mild proprietary blend of pine and fir extracts**.		31192 La Baya Dr.   Ste. C   Westlake Village, CA 91362
* Certified Organic ** Wild Harvested	  safe • effective • 100% natural ingredients • gentle	 8 04879 45910 1
	HOMEOPATHIC SALVE   NDC #	1 fl oz 30 ml
		<b>Customer Service: 818-851-9014</b>

**BABY ACNE**

calendula officinalis flower, sambucus nigra flower, thuja occidentalis salve

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52810-214
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD) (CALENDULA OFFICINALIS FLOWER - UNII:P0M7O4Y7YD)	CALENDULA OFFICINALIS FLOWER	1 [hp_X] in 100 mL
<b>SAMBUCUS NIGRA FLOWER</b> (UNII: 07V4DX094T) (SAMBUCUS NIGRA FLOWER - UNII:07V4DX094T)	SAMBUCUS NIGRA FLOWER	1 [hp_X] in 100 mL
<b>THUJA OCCIDENTALIS LEAF</b> (UNII: 0T0DQN8786) (THUJA OCCIDENTALIS LEAF - UNII:0T0DQN8786)	THUJA OCCIDENTALIS LEAF	1 [hp_X] in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>CANADA BALSAM</b> (UNII: K304VI98I3)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52810-214-11	30 mL in 1 JAR; Type 0: Not a Combination Product	10/18/2012	

## 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
PUREMEDY		003552251	manufacture(52810-214)