

BABY BALM- calendula officinalis, chamomilla recutita, archillea millefolium, symphytum officinalis, helianthus annuus salve
Spry Life LLC

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 Balm

OTC Purpose

Skin Protectant

Astringent

OTC Active Ingredients

Organic Achillea Millefolium (Yarrow) Flower Extract 1X (HPUS)

Organic Calendula Officinalis (Calendula) Flower Oil 1X (HPUS)

Organic Chamomilla Recutita (Matricaria) Flower 1X (HPUS)

Organic Symphytum Officinale (Comfrey) Leaf Powder 1X (HPUS)

Indications & Usage

- temporarily protects minor • diaper rash • baby acne
- helps prevent and temporarily protects and helps relieve • chapped or cracked skin
- helps protect from the drying effects of wind and cold weather
- temporarily protects and helps relieve minor skin irritation and itching due to • cradle cap • diaper rash • baby acne • eczema • psoriasis • rashes

Warnings

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For external use only.

- Do not use on • on deep wounds • animal bites • serious burns
- Stop use and ask a doctor if • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days
- When using this product keep out of eyes. Rinse with water to remove.

Keep Out of Reach of Children

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Storage and Handlin

Store at room temperature.

Dosage & Administration

Apply as often as needed to the affected area.

Inactive Ingredients

Organic Olea Europaea(Olive) Fruit Oil,Organic Cera Alba (Beeswax), Organic Helianthus Annuus (Sunflower) Seed Oil, Organic Simmondsia Chinensis (Jojoba) Seed Oil, Tocopherol (Vitamin E), Lavandula Angustifolia (Lavender) Oil.

Principal Display Panel



BABY BALM

calendula officinalis, chamomilla recutita, archillea millefolium, symphytum officinalis, helianthus annuus salve

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70994-501
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 51.7 g
SYMPHYTUM OFFICINALE WHOLE (UNII: H8FJJ6KX5Y) (SYMPHYTUM OFFICINALE WHOLE - UNII:H8FJJ6KX5Y)	SYMPHYTUM OFFICINALE WHOLE	1 [hp_X] in 51.7 g
CHAMOMILE (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	1 [hp_X] in 51.7 g
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA) (ACHILLEA MILLEFOLIUM FLOWER - UNII:YQR8R0SQEA)	ACHILLEA MILLEFOLIUM FLOWER	1 [hp_X] in 51.7 g

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
JOJOBA OIL (UNII: 724GKU717M)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70994-501-10	1 in 1 BOX	04/01/2016	
1	NDC:70994-501-02	51.7 g in 1 CAN; Type 0: Not a Combination Product		
2	NDC:70994-501-04	17 g in 1 TUBE; Type 0: Not a Combination Product	02/06/2019	
3	NDC:70994-501-08	113.4 g in 1 JAR; Type 0: Not a Combination Product	04/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/01/2016	

