

METADERM SCALP AND BODY- achillea millefolium, aesculus hippocastanum, berberis vulgaris, conium maculatum, matricaria chamomilla, phytolacca decandra, rhus toxicodendron, sanguinaria canadensis spray
Cosmetic Specialty Labs, Inc.

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.

Metaderm Scalp and Body Spray

Active Ingredient

Achillea millefolium (3X H.P.U.S.*, 0.04%)
Aesculus hippocastanum (3X H.P.U.S.*, 0.04%)
Berberis vulgaris (3X H.P.U.S.*, 0.09%)
Conium maculatum (3X H.P.U.S.*, 0.21%)
Matricaria chamomilla (3X H.P.U.S.*, 0.05%)
Phytolacca decandra (3X H.P.U.S.*, 0.11%)
Rhus toxicodendron (3X H.P.U.S.*, 0.13%)
Sanguinaria canadensis (3X H.P.U.S.*, 0.08%)

Purpose

Psoriasis relief

*The letters H.P.U.S. indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.

Uses:

Temporarily relieves the dryness, itching, flaking, rash, redness, and skin irritation associated with eczema, psoriasis, and dry skin.

Warnings:

for external use only

When using this product:

- Avoid contact with eyes.
- If swallowed, get medical help or contact a Poison Control Center immediately.
- Test for allergy by rubbing small amount on skin first.
- Do not use if allergic to or hypersensitive to any ingredient.
- If condition worsens or does not improve consult a doctor.

Keep all medicines out of reach of children.

Directions:

Apply liberally at least twice daily, maximal results observed in 12 weeks. If using topical steroids, Metaderm can be added. If stopping steroids, sudden withdrawal can result in flare, taper as necessary.

Other ingredients:

Purified Water, Hamamelis virginiana, Hydrastis canadensis, Avena sativa, Populus tremuloides, Populus alba, Cochlearia officinallis, Ervum lens, Veronica officinalis, Scrophularia nodosa, Sambucus nigra, Althaea officinalis, Malva sylvestris, Tussilago farfara, Smilax medica, Nasturtium officinale, Vincetoxicum officinale, Pimpinella saxifraga, Ethanol.


Principal Display Panel and Drug Facts

Drug Facts	
Active Ingredient	Purpose
Achillea millefolium (3X H.P.U.S.* 0.04%)	Eczema, Psoriasis, Seborrhea relief
Aesculus hippocastanum (3X H.P.U.S.* 0.04%)	Eczema, Psoriasis, Seborrhea relief
Berberis vulgaris (3X H.P.U.S.* 0.09%)	Eczema, Psoriasis, Seborrhea relief
Conium maculatum (3X H.P.U.S.* 0.21%)	Eczema, Psoriasis, Seborrhea relief
Matricaria chamomilla (3X H.P.U.S.* 0.05%)	Eczema, Psoriasis, Seborrhea relief
Phytolacca decandra (3X H.P.U.S.* 0.11%)	Eczema, Psoriasis, Seborrhea relief
Rhus toxicodendron (3X H.P.U.S.* 0.13%)	Eczema, Psoriasis, Seborrhea relief
Sanguinaria canadensis (3X H.P.U.S.* 0.08%)	Eczema, Psoriasis, Seborrhea relief
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Uses Temporarily relieves the dryness, itching, flaking, rash, redness, and skin irritation associated with eczema, psoriasis, and dry skin.	
Warnings for external use only.	
When using this product ■ avoid contact with the eyes.	
Keep all medicines out of the reach of children.	
If swallowed, get medical help or contact a Poison Control Center immediately.	
Test for allergy by rubbing small amount on the skin first. Do not use if allergic to or hypersensitive to any ingredient. If condition worsens or does not improve consult a doctor.	
Directions: Apply liberally at least twice daily maximal results observed in 12 weeks. If using topical steroids, Metaderm can be added. If stopping steroids, sudden withdrawal can result in flare, taper as necessary.	
Inactive ingredients Purified Water, Hamamelis virginiana, Hydrastis canadensis, Avena sativa, Populus tremuloides, Populus alba, Cochlearia officinallis, Ervum lens, Veronica officinalis, Scrophularia nodosa, Sambucus nigra, Althaea officinalis, Malva sylvestris, Tussilago farfara, Smilax medica, Nasturtium officinale, Vincetoxicum officinale, Pimpinella saxifraga, Ethanol.	

METADERMSM
www.metaderm.com



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 Oklahoma City, OK 73104 1-888-240-7095

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METADERM[®]

SCALP & BODY SPRAY
REFILL

APPLY **2X** DAILY

IMPROVEMENT
IN 2 WEEKS, CLEAR
SKIN IN 10-12
WEEKS

Eczema
& Seborrhea

32 fl. oz. (950 ml)

METADERM SCALP AND BODY

achillea millefolium, aesculus hippocastanum, berberis vulgaris, conium maculatum, matricaria chamomilla, phytolacca decandra, rhus toxicodendron, sanguinaria canadensis spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58133-380
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MATRICARIA CHAMOMILLA FLOWERING TOP OIL (UNII: SA8AR2W4ER) (MATRICARIA CHAMOMILLA FLOWERING TOP OIL - UNII:SA8AR2W4ER)	MATRICARIA CHAMOMILLA FLOWERING TOP OIL	5 [hp_M] in 1 mL
SANGUINARIA CANADENSIS ROOT (UNII: N9288CD508) (SANGUINARIA CANADENSIS ROOT - UNII:N9288CD508)	SANGUINARIA CANADENSIS ROOT	8 [hp_M] in 1 mL
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)	ACHILLEA MILLEFOLIUM	4 [hp_M] in 1 mL
BERBERIS VULGARIS FRUIT (UNII: 6XEF22AHC3) (BERBERIS VULGARIS FRUIT - UNII:6XEF22AHC3)	BERBERIS VULGARIS FRUIT	9 [hp_M] in 1 mL
CONIUM MACULATUM FRUIT (UNII: Y71WKJ3A2K) (CONIUM MACULATUM FRUIT - UNII:Y71WKJ3A2K)	CONIUM MACULATUM FRUIT	21 [hp_M] in 1 mL
RHUS SPP. WHOLE (UNII: 3U7FG9T9MW) (RHUS SPP. WHOLE - UNII:3U7FG9T9MW)	RHUS SPP. WHOLE	13 [hp_M] in 1 mL
PHYTOLACCA OCTANDRA LEAF (UNII: 0804KD28Q9) (PHYTOLACCA OCTANDRA LEAF - UNII:0804KD28Q9)	PHYTOLACCA OCTANDRA LEAF	11 [hp_M] in 1 mL
AESCULUS HIPPOCASTANUM SEED OIL (UNII: E0M52HIR1Y) (AESCULUS HIPPOCASTANUM SEED OIL - UNII:E0M52HIR1Y)	AESCULUS HIPPOCASTANUM SEED OIL	4 [hp_M] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
VERONICA OFFICINALIS LEAF (UNII: 96R87REA55)	
ALTHAEA OFFICINALIS LEAF (UNII: E2QQV92338)	
SCROPHULARIA NODOSA (UNII: 7H443NUB2T)	
WATER (UNII: 059QF0KO0R)	
1-(3,5-BIS(TRIFLUOROMETHYL)PHENYL)ETHANOL (UNII: 03H8X9K3I3)	
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)	
TUSSILAGO FARFARA (UNII: 0JXZ63016V)	
HYDRASTIS CANADENSIS WHOLE (UNII: R763EBH88T)	
SAMBUCUS NIGRA FLOWER OIL (UNII: Q35633V53D)	
MALVA SYLVESTRIS LEAF (UNII: 17H39B00T5)	
POPULUS TREMULOIDES LEAF (UNII: 7IHH57D9E0)	
POPULUS ALBA LEAF (UNII: A74CT64437)	
COCHLEARIA OFFICINALIS LEAF (UNII: WAG1VW36J6)	
SARSAPARILLA (UNII: 2H1576D5WG)	
NASTURTIUM OFFICINALE (UNII: YH89GMV676)	
VINCETOXICUM ATRATUM ROOT (UNII: 7DQZ24B35Y)	
PIMPINELLA SAXIFRAGA ROOT (UNII: 5Y05905N7G)	
LENS CULINARIS FRUIT (UNII: ZYZ076G9JH)	

AVENA SATIVA LEAF (UNII: 206P119V7R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-380-32	950 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2018	
2	NDC:58133-380-04	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/15/2018	

Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Registrant - Cosmetic Specialty Labs, Inc. (032973000)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty Labs, Inc.		032973000	manufacture(58133-380)

Revised: 8/2018

Cosmetic Specialty Labs, Inc.