

VIVALACARA DERMALERE ADVANCED BURN AND SCAR CREAM- coconut, chamomile, sunflower oil, dexpanthenol, plantago major, urtica dioica, cotinus coggygia, calendula officinalis flower cream
Bodywell Natural Skin Care 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.

Active Ingredients

Coconut oil, Chamomile, Calendula officinalis flower, Sunflower oil, Dexpanthenol, Plantago major, Urtica dioica, Cotinus coggygia

Purpose

Burn and Scar cream

Uses

This product contains Calendula. Calendula Officinalis is traditionally used in Herbal Medicine to aid in wound healing and help relieve skin inflammations and irritations. This product contains German Chamomile. Chamomilla Matricaria is used in Herbal Medicine to help relieve minor inflammation/or irritation of the skin.

Warnings

For external use only. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and consult a health care professional if symptoms worsen or last for more than 7 days.

Do not use this product if you are pregnant or breastfeeding.

Stop use if hypersensitivity/allergy or irritation occurs.

Keep out of reach of children.

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

Directions.

Adults: Apply to affected area or as needed.

Other Information.

Do not use on deep puncture wounds, animal bites or serious burns.

Inactive Ingredients.

Purified water(Water) Stearic Acid,(Palm Oil), Alcoholi(Corn Sugar), Oleyl Erucate(Rapeseed Oi l), Stearyl Alcoholi(Palm Oil), Glyceryl Monostearate(Palm Oil), Euphorbia Cerifera(Candelilla) Wax(Candelilla Plant), Capric/Caprylic Triglycerides(Coconut Oil), Hydroxypropyl Starch Phosphate(Corn Starch), LArginine(Giycine ~ax Plant), Hydrogenated Castor Oii(Castor Oil Plant), Dehydroacetic Acid(Organic Compound), Xanthan Gum(Giucose), Aloe Barbadensis Leaf Juice(Aioe Barbadensis Leaf)

Product label



VIVALACARA DERMALERE ADVANCED BURN AND SCAR CREAM			
coconut, chamomile, sunflower oil, dexpanthenol, plantago major, urtica dioica, cotinus coggygria, calendula officinalis flower cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81441-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COCONUT OIL (UNII: Q9L0O73W7L) (COCONUT OIL - UNII:Q9L0O73W7L)	COCONUT OIL	6 g in 100 mL
CHAMOMILE (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	1 g in 100 mL
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) (CALENDULA OFFICINALIS FLOWER - UNII:P0M7O4Y7YD)	CALENDULA OFFICINALIS FLOWER	1 g in 100 mL
SUNFLOWER OIL (UNII: 3W1JG795YI) (SUNFLOWER OIL - UNII:3W1JG795YI)	SUNFLOWER OIL	2 g in 100 mL
DEXPANTHENOL (UNII: 1O6C93RI7Z) (DEXPANTHENOL - UNII:1O6C93RI7Z)	DEXPANTHENOL	0.1 g in 100 mL
URTICA DIOICA LEAF (UNII: X6M0DRN46Q) (URTICA DIOICA LEAF - UNII:X6M0DRN46Q)	URTICA DIOICA LEAF	0.02 g in 100 mL
PLANTAGO MAJOR LEAF (UNII: 7DC28K241X) (PLANTAGO MAJOR LEAF - UNII:7DC28K241X)	PLANTAGO MAJOR LEAF	0.02 g in 100 mL
COTINUS COGGYGRIA LEAF (UNII: 8FB19JDF22) (COTINUS COGGYGRIA LEAF - UNII:8FB19JDF22)	COTINUS COGGYGRIA LEAF	0.02 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALCOHOL (UNII: 3K9958V90M)	
OLEYL ERUCATE (UNII: 753W099NQ6)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CANDELILLA WAX (UNII: WL0328HX19)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ARGININE (UNII: 94ZLA3W45F)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
STARCH, CORN (UNII: O8232NY3SJ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81441-007-01	40 mL in 1 TUBE; Type 0: Not a Combination Product	04/02/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/02/2021	

Labeler - Bodywell Natural Skin Care Inc (201162026)

Establishment

Name	Address	ID/FEI	Business Operations
Bodywell Natural Skin Care Inc		201162026	manufacture(81441-007)

Revised: 1/2023

Bodywell Natural Skin Care Inc