

**VIVALACARA DERMALERE ADVANCED SKIN CREAM- coconut, german chamomile, pot-marigold, helianthus annuus, d-panthenol, plantago major, urtica dioica, cotinus coggygria 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.*

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## **Active Ingredients**

Cocos nucifera, German chamomile, Pot-marigold, Helianthus Annuus, D-Panthenol, Plantago major, Urtica dioica, Cotinus coggygria

## **Purpose**

Fast Healing of Wounds & Damaged Skin  
Quick Relief of Skin Inflammation & Irritation  
Badge - made with calendula and chamomile

Lubricates, protects, and soothes dry, cracked, and chafed skin.  
Moisturizes and improves the look of recent scars.

## **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. Matricaria chamomilla 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. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Stop use if hypersensitivity/allergy or irritation occurs. Do not use this product if you are pregnant or breastfeeding.

## **Keep out of reach of children.**

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

## **Directions.**

Adults: Apply to affected area as needed.

**Other Information.**

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

**Inactive Ingredients.**

Purified water (Water), Stearic acid (Palm Oil), Alcohol (Corn Sugar), Oleyl erucate (Rapeseed Oil), Stearyl alcohol (Palm Oil), Glyceryl monostearate (Palm Oil), Euphorbia Cerifera (Candelilla) Wax (Candelilla Plant), Caprylic/capric triglyceride (Coconut Oil) Hydroxypropyl starch phosphate (Corn Starch) ,L-Arginine (Glycine Max Plant) ,Hydrogenated castor oil (Castor Oil Plant), Dehydroacetic Acid (Organic Compound), Xanthan Gum (Glucose),Aloe Barbadensis Leaf Juice (Aloe Barbadensis Leaf).

**Product label**



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### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81441-006	
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: 8FBI9JDF22) (COTINUS COGGYGRIA LEAF - UNII:8FBI9JDF22)		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:81441-006-01	50 mL in 1 TUBE; Type 0: Not a Combination Product	03/24/2021	
2	NDC:81441-006-02	40 mL in 1 TUBE; Type 0: Not a Combination Product	03/24/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/24/2021	

**Labeler -** Bodywell Natural Skin Care Inc (201162026)

## Establishment

Name	Address	ID/FEI	Business Operations
Bodywell Natural Skin Care Inc		201162026	manufacture(81441-006)

Revised: 1/2023

Bodywell Natural Skin Care Inc