

KORIUM WOUND CARE- calendula officinalis 1x hpus spray
GR8BIO 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.

Korium

Calendula Officinalis 1X HPUS -2%

Healing Agent

May help promote healing of minor cuts, scratches and chafing.

FOR EXTERNAL USE ONLY

DO NOT USE if you are allergic to Calendula officinalis or to any of this product's inactive ingredients.

WHEN USING THIS PRODUCT:

Avoid contact with eyes. If contact occurs, rinse thoroughly with water.

You may experience some transient mild pain on the wound area.

STOP USE AND ASK DOCTOR IF YOU:

Have any allergic reaction to this product.

Experience a deep or puncture wound, animal bite, or serious burn.

KWEEP OUT OF REACH OF CHILDREN. If swallowed get medical help or contact a poison control center right away.

DIRECTIONS

- clean affected area thoroughly before applying
- apply spray twice a day (every 12 hours) on affected area until entirely covered.
- let dry and cover with a sterile bandage to promote healing.
- continue use as needed

OTHER INFORMATION

Store at room temperature 68-77°F (20-25°C).

Do not use if tamper evident seal is broken.

Butylated Hydroxytoluene

Ethanol

Polyethylene Glycol

Purified Water



Drug Facts	
Active ingredient: Calendula officinalis 1 X HPUS-2%	Purpose: Healing agent
Uses ■ May help promote healing of minor cuts, scratches, and chafing.	
Warnings For external use only. Do not use if you are allergic to Calendula officinalis or to any of this product's inactive ingredients.	
When using this product ■ avoid contact with eyes. If contact occurs, rinse thoroughly with water. ■ you may experience some transient mild pain on the wound area.	
Stop use and ask a doctor if you ■ have any allergic reaction to this product. ■ experience a deep or puncture wound, animal bite, or serious burn.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions ■ clean affected area thoroughly before applying. ■ apply spray twice a day (every 12 hours) on affected area until entirely covered. ■ let dry and cover with a sterile bandage to promote healing. ■ continue use as needed.	
Other information ■ store at room temperature 68-77°F (20-25°C). ■ do not use if tamper-evident seal is broken.	
Inactive ingredients butylated hydroxytoluene, ethanol, polyethylene glycol, purified water.	
If you experience serious wounds, seek immediate medical attention. For question or to report adverse events call: 888-317-8074	

KORIUM WOUND CARE			
calendula officinalis 1x hpus spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70811-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	CALENDULA OFFICINALIS WHOLE (UNII: PFR03EBU0H) (CALENDULA OFFICINALIS WHOLE - UNII:PFR03EBU0H)	CALENDULA OFFICINALIS WHOLE	1 [hp_X] in 20 mL
Inactive Ingredients			
	Ingredient Name		Strength
	WATER (UNII: 059QF0K00R)		
	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)		
	ALCOHOL (UNII: 3K9958V90M)		

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70811-001-00	20 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	12/20/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/20/2016	

Labeler - GR8BIO LLC (080291999)

Registrant - Homeocare Laboratories Inc. (088248828)

Establishment

Name	Address	ID/FEI	Business Operations
Homeocare Laboratories Inc.		088248828	manufacture(70811-001)

Revised: 1/2020

GR8BIO LLC