

PROSIRONA- calendula officinalis flowering top oil
Atlantic Management Resources 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.

ProSirona

Active ingredients:	Calendula Oil (1x)
Warnings:	<ul style="list-style-type: none">> For external use only.> Keep out of reach of children, and do not use on children under 5 years of age.> If pregnant, nursing or taking oral contraceptives, seek advice of a health professional before use.
Inactive ingredients:	Almond oil; Alpha-Pinene; Beta-Pinene; Coriander Oil; Cornmint Oil; Menthyl-Acetate; Mineral Oil; Orange Oil; Pennyroyal Oil; Rosemary Oil and White Camphor.
Warnings:	<ul style="list-style-type: none">> For external use only.> Keep out of reach of children, and do not use on children under 5 years of age.> If pregnant, nursing or taking oral contraceptives, seek advice of a health professional before use.
Uses:	Temporarily relieves pain associated with minor aches and pains of muscles, joints, nerve-based pain and headaches/migraines. Individual results may vary.
Directions:	<ul style="list-style-type: none">> When you are ready to apply Neuroquell®, remove the cap, turn the bottle upside down, and gently roll the applicator onto the area of discomfort in a continuous, back-and-forth motion to cover approximately one-half of the area of your pain. If using either the sample swab or towelette, apply in a similar way. Your skin will remain moist for a few minutes.> Close cap tightly after use, and wash hands thoroughly.> Feel free to reapply 4-to-6 hours later and up to 3 additional times per day.> To eliminate the peppermint scent, you can wash the treated area with soap and water 15 minutes after the application. This will not affect the efficacy of the product.
Uses:	Temporarily relieves pain associated with minor aches and pains of muscles, joints, nerve-based pain and headaches/migraines. Individual results may vary.

Patented

NDC 66233-713-01

ProSirona

LIMITED TEMPORARY RELIEF FROM
THE DISCOMFORT OF ENDOMETRIOSIS
AND FIBROMYALGIA
A Homeopathic Formula

Remove twist-off cap. Apply a liberal amount by gently rolling the top of the self-dispensing vial to the general area of discomfort. For external use only.

Active Ingredients: Calendula Oil 1X

Dist. by: Endometriosis Assoc. Inc. (International)

Mfg. by: Claire Ellen Topicals

PO Box 901 Westborough, MA 01581 USA

Net Wt: 1/8 fl. Oz. (3.5 gm.)

Lot Code B-02

www.bestpainrelief.com
www.endometriosisassn.org

PROSIRONA			
calendula officinalis flowering top oil			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66233-713
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)		CALENDULA OFFICINALIS FLOWERING TOP	0.0035 g in 1 g
Inactive Ingredients			
Ingredient Name		Strength	
CAMPHOR OIL, WHITE (UNII: 26P3H26Z9X)		0.05 g in 1 g	
CORIANDER OIL (UNII: 7626GC95E5)		0.002 g in 1 g	
ROSEMARY OIL (UNII: 8LGU7VM393)		0.06 g in 1 g	
MINERAL OIL (UNII: T5L8T28FGP)		0.001 g in 1 g	
MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)		0.8315 g in 1 g	
PENNYROYAL OIL (UNII: AK85U7Y3MV)		0.04 g in 1 g	
ORANGE OIL (UNII: AKN3KSD11B)		0.007 g in 1 g	
ALMOND OIL (UNII: 66YXD4DKO9)		0.005 g in 1 g	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66233-713-01	1 g in 1 BOTTLE, WTH APPLICATOR; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	07/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/04/2001	

Labeler - Atlantic Management Resources Inc. (959409855)

Registrant - Atlantic Management Resources Inc. (959409855)

Establishment

Name	Address	ID/FEI	Business Operations
Atlantic Management Resources Inc.		959409855	manufacture(66233-713)

Revised: 7/2022

Atlantic Management Resources Inc.