

CALIFLORA- calendula officinalis gel
Schwabe North America, 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.

Califlora

Active ingredient

Contains 10% CALENDULA OFFICINALIS 1X

Inactive Ingredient

CARBOMER
ETHYL ALCOHOL
PURIFIED WATER
SODIUM HYDROXIDE
WITCH HAZEL DISTILLATE

Dosage & Administration

Apply thin layer to affected area. For best results, use promptly after injury or trauma occurs.

For minor burns, first run cool water on the burn area and dry.

For minor skin irritation, first wash the area with mild soap, rinse and dry.

Adults and children 2 years of age and older: Apply to affected area. Repeat as necessary.

Children under 2 years of age: Consult a doctor

Patch test recommended on sensitive skin.

Indications and Use

Temporarily relieves pain and itch associated with sunburn, windburn and chapped skin. Helps promote healing of minor burns and skin irritations.

Purpose

Temporarily relieves pain and itch associated with sunburn, windburn and chapped skin. Helps promote healing of minor burns and skin irritations.

Warning

For external use only. Avoid contact with eyes.

Do not use

Do not use on broken skin. Do not use if hypersensitive to any ingredients in this product.

Breast-feeding women should not apply to breast area.

Ask doctor

Ask a doctor before use in case of deep cuts or puncture wounds, animal bites or serious burns.

Pregnancy or breast feeding

If pregnant or breast-feeding, ask a healthcare professional before use.

Keep out of reach children

Keep out of reach of children.

Overdose

If swallowed, seek medical help or contact a Poison Control Center immediately.



CALIFLORA

calendula officinalis gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53499-5190
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	1 [hp_X] in 78 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WITCH HAZEL (UNII: 101I4J0U34)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-5190-8	1 in 1 CARTON	01/01/2006	03/31/2025
1		78 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:53499-5190-4	1 in 1 CARTON	01/01/2006	03/31/2025
2		28 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/01/2006	03/31/2025

Labeler - Schwabe North America, Inc (831153908)

Establishment

Name	Address	ID/FEI	Business Operations
Schwabe Mexico, S.A. de C.V.		812805901	manufacture(53499-5190)

Revised: 5/2022

Schwabe North America, Inc