

FLORASONE- cardiospermum halicacabum flowering top cream
Schwabe North America

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.

Florasone

Active Ingredient

Contains 10% Cardiospermum halicacabum tincture

Inactive Ingredient

Benzyl Alcohol

Cetyl Alcohol

Ethyl Alcohol

Glycerin

Glycol Stearate

Isopropyl Myristate

Mineral Oil

Potassium Hydroxide

Purified Water

Stearyl Heptanoate

Dosage & Administration

Directions

Adults & children 6 years of age and older: apply to affected area up to 4 times daily; rub in gently.

Patch test recommended on sensitive skin.

Indications and Usage

Temporarily relieves itch, rash, and skin irritation/inflammation.

Purpose

Temporarily relieves itch, rash, and skin irritation/inflammation.

Warnings

For external use only.

Avoid contact with eyes and broken skin.

Do Not Use

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

Breast-feeding woman should not apply to breast area.

Stop Use

Stop use and ask a doctor if increased skin irritation, rash or other allergic reaction develops, condition worsens or does not improve within 7 days, symptoms clear up and occur again within a few days.

These could be signs of a serious condition.

Pregnancy or Breast-feeding

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

Keep out of reach of children

Keep out of reach of children.

Overdose

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



Add image transcription here...

FLORASONE

cardiospermum halicacabum flowering top cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53499-0390
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARDIOSPERMUM HALICACABUM FLOWERING TOP (UNII: MZP2508BRR) (CARDIOSPERMUM HALICACABUM FLOWERING TOP - UNII:MZP2508BRR)	CARDIOSPERMUM HALICACABUM FLOWERING TOP	1 [hp_X] in 28 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MINERAL OIL (UNII: T5L8T28FGP)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0K00R)	
STEARYL HEPTANOATE (UNII: 2M4UGL1NCN)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-0390-4	1 in 1 CARTON	01/01/2006	
1		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	

Labeler - Schwabe North America (831153908)**Establishment**

Name	Address	ID/FEI	Business Operations
Schwabe Mexico, S.A. de C.V.		812805901	manufacture(53499-0390)