

TRIFLORA- urtica doicia, rhus toxicodendron, ledum palustre 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.

Triflora

Active Ingredients

Contains 5% Ledum palustre 2X

Contains 12.5% Urtica dioica 1X

Contains 2.5% Rhus tox 4X

Inactive Ingredient

carbomer

ethyl alcohol

pine needle oil

purified water

sodium hydroxide

witch hazel distillate

Dosage and Administration

Directions

Adult and 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 & Usage

Temporarily relieves minor aches, pains, and joint/muscle stiffness associated with arthritis, rheumatism, simple backache and tendinitis.

Purpose

Temporarily relieves minor aches, pains, and joint/muscle stiffness associated with arthritis, rheumatism, simple backache and tendinitis.

Warnings

For external use only.

Avoid contact with eyes and broken skin.

Do Not Use

Do not use if hypersensitive to Poison Ivy (Rhus tox) or any other ingredient in this product, in breast area when breast-feeding.

Stop Use

Stop use and ask a doctor if 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...

TRIFLORA

urtica doicia, rhus toxicodendron, ledum palustre gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53499-7290
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
		1.55g X1

URTICA DIOICA (UNII: 710FLW4U46) (URTICA DIOICA - UNII:710FLW4U46)	URTICA DIOICA	1 [hp_X] in 77 g
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	4 [hp_X] in 77 g
LEDUM PALUSTRE twig (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWIG - UNII:877L01IZ0P)	LEDUM PALUSTRE twig	2 [hp_X] in 77 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
ALCOHOL (UNII: 3K9958V90M)	
PINE NEEDLE OIL (PINUS SYLVESTRIS) (UNII: 5EXL5H740Y)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WITCH HAZEL (UNII: 101I4J0U34)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-7290-8	1 in 1 CARTON	10/01/2021	
1		77 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:53499-7290-4	1 in 1 CARTON	10/01/2021	09/30/2025
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		10/01/2021	

Labeler - Schwabe North America, Inc (831153908)

Establishment

Name	Address	ID/FEI	Business Operations
Schwabe Mexico SA DE CV		812805901	manufacture(53499-7290)

Revised: 3/2023

Schwabe North America, Inc