

ARNIFLORA - arnica montana 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.

Arniflora

Active Ingredient

ARNICA MONTANA 1X

Inactive Ingredient

carbomer

ethyl alcohol

purified water

sodium hydroxide

witch hazel distillate

Dosage and Administration

Directions

Apply thin layer to affected area. Massage gently or use compress.

For best results, use promptly after injury or trauma occurs

Adults and children 6 years of age and older: apply to affected area up to 4 times daily

Patch test recommended on sensitive skin

Indications & Usage

Temporarily relieves muscle pain, stiffness, and swelling associated with overexertion, sprains, falls, blows, and minor sports injuries.

Reduces pain, swelling, and discoloration from bruises.

Purpose

Temporarily relieves muscle pain, stiffness, and swelling associated with overexertion, sprains, falls, blows, and minor sports injuries.

Reduces pain, swelling, and discoloration from bruises.

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, 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.

Pregnant 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...

ARNIFLORA

arnica montana gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53499-5090
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ARNICA MONTANA (UNII: O80TY208Z W) (ARNICA MONTANA - UNII:O80TY208Z W)		ARNICA MONTANA	1 [hp_X] in 28 g	
Inactive Ingredients				
Ingredient Name			Strength	
ALCOHOL (UNII: 3K9958V90M)				
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)				
WATER (UNII: 059QF0KO0R)				
WITCH HAZEL (UNII: 101I4J0U34)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53499-5090-4	1 in 1 CARTON	01/01/2011	05/31/2026
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:53499-5090-8	1 in 1 CARTON	01/01/2011	
2		78 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		01/01/2011		

Labeler - Schwabe North America, Inc (831153908)

Establishment			
Name	Address	ID/FEI	Business Operations
Schwabe Mexico, S.A. de C.V.		812805901	manufacture(53499-5090)

Revised: 9/2023

Schwabe North America, Inc