

INJURY TOPICAL- calendula officinalis, arnica montana, hypericum perforatum, symphytum officinale, bellis perennis, carbo vegetabilis, hamamelis virginiana, millefolium, rhus tox, ruta graveolens, veratrum album gel
BioActive Nutritional, 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.

Drug Facts:

ACTIVE INGREDIENTS:

Calendula Officinalis MT, Arnica Montana MT, 3X, Hypericum Perforatum 3X, 12X, Symphytum Officinale 6X, Bellis Perennis 12X, Carbo Vegetabilis 12X, Hamamelis Virginiana 12X, Millefolium 12X, Rhus Tox 12X, Ruta Graveolens 12X, Veratrum Album 12X.

INDICATIONS:

For bumps, bruises, abrasions, strains, sprains, fractures, stiffness. For all body and head injuries.

WARNINGS:

For External Use Only

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Do not use if tamper evident seal is broken or missing.

Store in cool, dry place.

KEEP OUT OF REACH OF CHILDREN:

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

Apply small amount every 10 minutes for 3 doses immediately after injury, then 2-3 times daily.

INDICATIONS:

For bumps, bruises, abrasions, strains, sprains, fractures, stiffness. For all body and head injuries.

INACTIVE INGREDIENTS:

Aloe Barbadensis Leaf Juice, Water, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Ethanol

QUESTIONS:

Distributed by:
BioActive Nutritional, Inc.
1803 N. Wickham Rd.
Melbourne, FL 32935
bioactivenutritional.com

PACKAGE LABEL DISPLAY:

BIOActive Nutritional
INJURY TOPICAL
HOMEOPATHIC
NET WT 2 OZ (56.7 g)



WARNINGS: If pregnant or breast-feeding, ask a health care professional before use. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. Do not use if tamper evident seal is broken or missing. Store in a cool, dry place.

LOT:

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INJURY TOPICAL

HOMEOPATHIC

ACTIVE INGREDIENTS:

Calendula MT, Arnica MT, 3X, Hypericum 3X, 12X, Symphytum 6X, Bellis 12X, Carbo Veg 12X, Hamamelis 12X, Millefolium 12X, Rhus Tox 12X, Ruta 12X, Veratrum Alb 12X.

INACTIVE INGREDIENTS:

Aloe Vera Gel (Aloe Barbadensis Leaf Juice, Water, Benzyl Alcohol [and] Ethylhexylglycerin [and] Tocopherol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Disodium EDTA, Sodium Hydroxide), Demineralized Water, Ethanol.

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INJURY TOPICAL

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Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:43857-0400

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 1 g
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	1 [hp_X] in 1 g
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	3 [hp_X] in 1 g
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	6 [hp_X] in 1 g
BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	12 [hp_X] in 1 g
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10) (ACTIVATED CHARCOAL - UNII:2P3VWU3H10)	ACTIVATED CHARCOAL	12 [hp_X] in 1 g
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS) (HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK	12 [hp_X] in 1 g
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)	ACHILLEA MILLEFOLIUM	12 [hp_X] in 1 g
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	12 [hp_X] in 1 g
RUTA GRAVEOLENS FLOWERING TOP (UNII: N94C2U587S) (RUTA GRAVEOLENS FLOWERING TOP - UNII:N94C2U587S)	RUTA GRAVEOLENS FLOWERING TOP	12 [hp_X] in 1 g
VERATRUM ALBUM ROOT (UNII: QNS6W5US1Z) (VERATRUM ALBUM ROOT - UNII:QNS6W5US1Z)	VERATRUM ALBUM ROOT	12 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43857-0400-1	56.7 g in 1 TUBE; Type 0: Not a Combination Product	09/01/2016	07/08/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		09/01/2016	07/08/2024

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apothecca Company (844330915)**Establishment**

Name	Address	ID/FEI	Business Operations
Apothecca Company		844330915	manufacture(43857-0400) , api manufacture(43857-0400) , label(43857-0400) , pack(43857-0400)

Revised: 5/2021

BioActive Nutritional, Inc.