

BURN AIDE- calendula officinalis, hypericum perforatum, arsenicum album, belladonna, cantharis, causticum, picricum acidum, urtica urens spray
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, Hypericum Perforatum MT, 30X, Arsenicum Album 12X, Belladonna 12X, Cantharis 12X, Causticum 12X, Picricum Acidum 12X, Urtica Urens 12X.

INDICATIONS:

For temporary relief of minor burns.

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.

Do not get in your eyes. If you get Burn Aide in your eyes, rinse immediately with cool tap water. In case of serious burns, consult a doctor. If your symptoms do not get better in seven days or if they get worse, check with your doctor.

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:

Clean the affected area. Spray on affected area as needed.

INDICATIONS:

For temporary relief of minor burns.

INACTIVE INGREDIENTS:

Demineralized Water, Aloe Vera Thickened Gel (Aloe Barbadensis Leaf Juice, Water, Benzyl Alcohol (and) Ethylhexylglycerin (and) Tocopherol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Disodium EDTA Sodium Hydroxide), 10.7% Ethanol.

QUESTIONS:

Distributed by:

BioActive Nutritional, Inc.

1803 N. Wickham Rd.

Melbourne, FL 32935

bioactivenutritional.com

PACKAGE LABEL DISPLAY:

BIOActive Nutritional

BURN AIDE

HOMEOPATHIC

4 FL OZ (120 ml)



WARNINGS: 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 a cool, dry place.

LOT:

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

BURN AIDE

HOMEOPATHIC

ACTIVE INGREDIENTS:

Calendula Officinalis MT, Hypericum Perforatum MT, 30X, Arsenicum Album 12X, Belladonna 12X, Cantharis 12X, Causticum 12X, Picricum Acidum 12X, Urtica Urens 12X.

INACTIVE INGREDIENTS:

Water, Ethanol, Aloe Vera Leaf Juice Extract, Benzyl Alcohol, Ethylhexylglycerin, Tocopherol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Disodium EDTA, Sodium Hydroxide.

4 FL OZ (120 ml)

INDICATIONS:

For temporary relief of minor burns.

DIRECTIONS:

Clean the affected area. Spray on affected area as needed.

WARNINGS: Do not get in your eyes. If you get Burn Aide in your eyes, rinse immediately with cool tap water. In case of serious burns, consult a doctor. If your symptoms do not get better in seven days or if they get worse, check with your doctor.

BURN AIDE

calendula officinalis, hypericum perforatum, arsenicum album, belladonna, cantharis, causticum, picricum acidum, urtica urens spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0472
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA	CALENDULA OFFICINALIS	1 [hp_X]

OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	FLOWERING TOP	in 1 mL
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	1 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	12 [hp_X] in 1 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	12 [hp_X] in 1 mL
LYTTA VESICATORIA (UNII: 3Q034RO3BT) (LYTTA VESICATORIA - UNII:3Q034RO3BT)	LYTTA VESICATORIA	12 [hp_X] in 1 mL
CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)	CAUSTICUM	12 [hp_X] in 1 mL
PICRIC ACID (UNII: A49OS0F91S) (PICRIC ACID - UNII:A49OS0F91S)	PICRIC ACID	12 [hp_X] in 1 mL
URTICA URENS (UNII: IHN2NQ5OF9) (URTICA URENS - UNII:IHN2NQ5OF9)	URTICA URENS	12 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43857-0472-1	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/13/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/13/2018	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0472) , api manufacture(43857-0472) , label(43857-0472) , pack(43857-0472)

