

BURN AIDE- calendula officinalis, hypericum perforatum, arsenicum album, belladonna, cantharis, causticum, kali bichromicum, picricum acidum, urtica urens spray
Energique, 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:

(in each drop): 8.31% of Arsenicum Album 12X, Belladonna 12X, Cantharis 12X, Causticum 12X, Hypericum Perforatum 30X, Kali Bichromicum 12X, Picricum Acidum 12X, Urtica Urens 12X; 1.75% of Calendula Officinalis 1X, Hypericum Perforatum 1X.

PURPOSE:

May temporarily relieve itching, pain, and swelling associated with minor burns.**

**Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

USES:

May temporarily relieve itching, pain, and swelling associated with minor burns.**

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WARNINGS:

For external use only.

If pregnant or breast-feeding, ask a health 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.

KEEP OUT OF REACH OF CHILDREN:

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

Spray on affected area as needed. Shake well before using.

INACTIVE INGREDIENTS:

Water, Ethanol, Glycerin, Aloe vera leaf juice extract, Benzyl alcohol, Ethylhexylglycerin, Tocopherol, Acrylates/C10-30 alkyl acrylate crosspolymer, Disodium EDTA, Sodium hydroxide.

QUESTIONS:

Dist. by Energique, Inc.
201 Apple Blvd
Woodbine, IA 51579 800-869-8078

PACKAGE LABEL DISPLAY:

ENERGIQUE

SINCE 1987

HOMEOPATHIC REMEDY

BURN AIDE

SPRAY

6 fl. OZ. (180 ml)

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LOT: XXXXXX MFD: MM/YY

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44911-0662
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 mL
HYPERICUM PERFORATUM WHOLE (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM WHOLE	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
POTASSIUM DICHROMATE (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V)	POTASSIUM DICHROMATE	12 [hp_X] in 1 mL
PICRIC ACID (UNII: A49OS0F91S) (PICRIC ACID - UNII:A49OS0F91S)	PICRIC ACID	12 [hp_X] in 1 mL
URTICA URENS WHOLE (UNII: IHN2NQ5OF9) (URTICA URENS - UNII:IHN2NQ5OF9)	URTICA URENS WHOLE	12 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
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:44911-0662-1	180 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/18/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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unapproved homeopathic		11/18/2022	
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Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(44911-0662) , api manufacture(44911-0662) , label(44911-0662) , pack(44911-0662)

Revised: 11/2022

Energique, Inc.