

TRAUMA PLUS GEL- calendula officinalis, arnica montana, hypericum perforatum, symphytum officinale, bellis perennis, ledum palustre, sulphuricum acidum, calcarea fluorica, ferrum phosphoricum, rhus tox, ruta graveolens, natrum sulphuricum gel
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:

Calendula Officinalis 1X, Arnica Montana 1X, 30C, Hypericum Perforatum 1X, 30C, Symphytum Officinale 6X, Bellis Perennis 12X, Ledum Palustre 12X, Sulphuricum Acidum 12X, Calcarea Fluorica 30X, Ferrum Phosphoricum 30X, Rhus Tox 30X, Ruta Graveolens 30X, Natrum Sulphuricum 30C.

INDICATIONS:

For temporary relief of pain associated with bumps, bruises, abrasions, strains, sprains, fractures, stiffness; for all minor injuries.**

**These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

WARNINGS:

For external use only. If an adverse reaction occurs, discontinue use.

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. Do not expose product to extreme temperatures.

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:

Apply small amount every 10 minutes for 3 doses immediately after injury, then 2 to 3 times daily. For topical use only.

INDICATIONS:

For temporary relief of pain associated with bumps, bruises, abrasions, strains, sprains, fractures, stiffness; for all minor injuries.**

**These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

INACTIVE INGREDIENTS:

Purified Water, Whey Protein Concentrate (milk), Benzyl Alcohol, Ethylhexylglycerin, Tocopherol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer (Carbopol (Ultrez 21), Aloe Barbadensis Leaf Juice (Aloe Vera 10X Concentrate), Sodium Hydroxide (Solution), Edetate Disodium (EDTA).

QUESTIONS:

Dist. by Energique, Inc., 201 Apple Blvd.
Woodbine, IA 51579 800.869.8078

PACKAGE LABEL DISPLAY:

ENERGIQUE

SINCE 1987

HOMEOPATHIC REMEDY

TRAUMA+GEL

Net wt. 2 oz. (57 g)

WARNINGS: For external use only. If an adverse reaction occurs, discontinue use. 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. Do not expose product to extreme temperatures.

INDICATIONS: May temporarily relieve pain associated with bumps, bruises, abrasions, strains, sprains, fractures, stiffness; for all minor injuries.**

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

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HOMEOPATHIC REMEDY

TRAUMA+GEL™

Net wt. 2 oz. (57 g)

Active Ingredients: Calendula 1X, Arnica 1X, 30C, Hypericum 1X, 30C, Symphytum 6X, Bellis 12X, Ledum 12X, Sulphuricum Ac 12X, Calc Fluor 30X, Ferrum Phos 30X, Rhus Tox 30X, Ruta 30X, Nat Sulphuricum 30C.

Inactive Ingredients: Purified Water, Whey Protein Concentrate (milk), Benzyl Alcohol (and) Ethylhexylglycerin (and) Tocopherol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Sodium Hydroxide, Disodium EDTA.

DIRECTIONS: Apply small amount every 10 minutes for 3 doses immediately after injury, then 2 to 3 times daily. For topical use only.

LOT: XXXXX

TRAUMA PLUS GEL

calendula officinalis, arnica montana, hypericum perforatum, symphytum officinale, bellis perennis, ledum palustre, sulphuricum acidum, calcarea fluorica, ferrum phosphoricum, rhus tox, ruta graveolens, natrum sulphuricum gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44911-0446
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	1 [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
LEDUM PALUSTRE TWIG (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWIG - UNII:877L01IZ0P)	LEDUM PALUSTRE TWIG	12 [hp_X] in 1 g
SULFURIC ACID (UNII: O40UQP6WCF) (SULFURIC ACID - UNII:O40UQP6WCF)	SULFURIC ACID	12 [hp_X] in 1 g
CALCIUM FLUORIDE (UNII: O3B55K4YK) (FLUORIDE ION - UNII:Q80VPU408O)	CALCIUM FLUORIDE	30 [hp_X] in 1 g
FERROSO FERRIC PHOSPHATE (UNII: 91GQH8I5F7) (FERROSO FERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERROSO FERRIC PHOSPHATE	30 [hp_X] in 1 g
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	30 [hp_X] in 1 g
RUTA GRAVEOLENS FLOWERING TOP (UNII: N94C2U587S) (RUTA GRAVEOLENS FLOWERING TOP - UNII:N94C2U587S)	RUTA GRAVEOLENS FLOWERING TOP	30 [hp_X] in 1 g
SODIUM SULFATE (UNII: 0YPR65R21J) (SODIUM SULFATE ANHYDROUS - UNII:36KCS0R750)	SODIUM SULFATE	30 [hp_C] in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
WHEY (UNII: 8617Z5FMF6)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44911-0446-1	57 g in 1 TUBE; Type 0: Not a Combination Product	02/08/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		02/08/2018	

Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(449 11-0446) , api manufacture(449 11-0446) , label(449 11-0446) , pack(449 11-0446)

Revised: 2/2018

Energique, Inc.