

TRAUMA PLUS GEL- not applicable 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 3X, 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 bumps, bruises, abrasions, strains, sprains, fractures, stiffness; for all body 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.

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For temporary relief of bumps, bruises, abrasions, strains, sprains, fractures, stiffness; for all body injuries**

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INACTIVE INGREDIENTS:

Alcohol, Biosaccharide Gum-1 (natural moisturizer derived from sorbitol) Carbomer (polymer), Glycerin, NaPCA (natural hydration factor), Sodium Hydroxymethylglycinate (preservative derived from amino acid glycine), Tromethamine (amine based organic buffer), Water

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)

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LOT: XXXXXXXXXXXX



HOMEOPATHIC REMEDY

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Inactive Ingredients: Alcohol, biosaccharide gum-1 (natural moisturizer derived from sorbitol), carbomer (polymer), glycerin, NaPCA (natural hydration factor), sodium hydroxymethylglycinate (preservative derived from amino acid glycine), tromethamine (amine based organic buffer), water.

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

TRAUMA PLUS GEL

not applicable gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:449 11-0124
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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	3 [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
ALCOHOL (UNII: 3K9958V90M)	
BIO SACCHARIDE GUM-1 (UNII: BB4PU4V09H)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
SODIUM HYDROXYMETHYLGLYCINATE (UNII: DIG6BWZ9XT)	
TROMETHAMINE (UNII: 023C2WHX2V)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:449 11-0124-1	57 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/18/2014	

Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(449 11-0 124) , api manufacture(449 11-0 124) , label(449 11-0 124) , pack(449 11-0 124)

Revised: 7/2014

Energique, Inc.