

**HEADACHE PAIN AND SINUS PRESSURE RELIEF- calendula officinalis, croton tiglium, natum muriaticum, plantago major, rhus tox, sarsaparilla (smilax regelii) 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:

CALENDULA OFFICINALIS 12X, CROTON TIGLIUM 30X, NATRUM MURIATICUM 30X, PLANTAGO MAJOR 30X, RHUS TOX 30X, SARSAPARILLA (SIMILAX REGELII) 30X

INDICATIONS:

May temporarily relieve pain due to inflammation caused by but not limited to the following: pressure, tension, trauma.**

**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 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 get into eyes.

If symptoms persist, consult a doctor.

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

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:

Adults and children spray liberally on affected area as needed. If symptoms persist, consult your health care professional. Consult a physician for use in children under 12 years of age.

INDICATIONS:

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INACTIVE INGREDIENTS:

ALOE BARBADENSIS LEAF JUICE (ALOE VERA 10X CONCENTRATE), (FLOWER)* ARNICA MONTANA (FLOWER)*, LARREA TRIDENTATA, (LEAF)* SYMPHYTUM OFFICINALE (LEAF)*, CROTON LECHLERI(SAP), INSTANTIZED SOLUBLE EGG SHELL MEMBRANE + (BIOVADERM BRAND WITH 1% SUNFLOWER LECITHIN), LAVANDULA ANGUSTIFOLIA (BUDS)*, IONIC COLLOIDAL SILVER BASE, MELISSA OFFICINALIS (LEAF)*, PEG-33, PEG-8 DIMETHICONE, PEG-14 (SILSENSE COPOLYOL-1 SILICONE), PHENOXYETHANOL, CAPRYLYL GLYCOL, SORBIC ACID, (OPTIPHEN-PLUS), PHYTOLACCA AMERICANA (BERRIES)*, PHYTOLACCA AMERICANA (ROOT)*, POTASSIUM SORBATE, PURIFIED WATER, SODIUM BICARBONATE, HYPERICUM PERFORATUM (AERIAL PARTS)*, TOCOPHEROL [VITAMIN E OIL] (DERIVED FROM SOY BEAN), VITAMIN C POWDER (ASCORBIC ACID), WHEY PROTEIN CONCENTRATE (RRB-117), SALIX ALBA(BARK)*, ACHELLEA MILLEFOLIUM (FLOWER)*

*Extract

QUESTIONS:

Dist. by Energique, Inc., 201 Apple Blvd.

Woodbine, IA 51579 800.869.8078

PACKAGE LABEL DISPLAY:

ENERGIQUE

SINCE 1987

HOMEOPATHIC REMEDY

HEADACHE PAIN & SINUS PRESSURE RELIEF

Topical Spray

1 fl. oz. (30 ml)

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

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LOT: XXXXXXXXXX



HOMEOPATHIC REMEDY

HEADACHE PAIN & SINUS PRESSURE RELIEF

Topical Spray

1 fl. oz. (30 ml)

Active Ingredients: Calendula 12X, Croton 30X, Nat Mur 30X, Plantago 30X, Rhus Tox 30X, Sarsaparilla 30X.

Inactive Ingredients: Aloe Barbadensis Leaf Juice, Arnica Flower*, Chaparral Leaf*, Comfrey Leaf*, Dragon's Blood Croton Sap, Eggshell Membrane, English Lavender Buds*, Ionic Colloidal Silver, Lemon Balm Leaf*, PEG-33 & PEG-8 Dimethicone & PEG-14, Phenoxyethanol & Caprylyl Glycol & Sorbic Acid, Poke Berries*, Poke Root*, Potassium Sorbate, Purified Water, Sodium Bicarbonate, St. John's Wort Aerial Parts*, Tocopherol (soy), Vitamin C, Whey Protein Concentrate (milk), White Willow Bark* and Yarrow Flower*.

DIRECTIONS: Adults and children spray liberally on affected area as needed. If symptoms persist, consult your health care professional. Consult a physician for use in children under 12 years of age.

HEADACHE PAIN AND SINUS PRESSURE RELIEF

calendula officinalis, croton tiglium, natum muriaticum, plantago major, rhus tox, sarsaparilla (smilax regelii) spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:449 11-0134
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	12 [hp_X] in 1 mL
CROTON TIGLIUM SEED (UNII: 0HK2GZK66E) (CROTON TIGLIUM SEED - UNII:0HK2GZK66E)	CROTON TIGLIUM SEED	30 [hp_X] in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	30 [hp_X] in 1 mL
PLANTAGO MAJOR (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII:W2469WNO6U)	PLANTAGO MAJOR	30 [hp_X] in 1 mL
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	30 [hp_X] in 1 mL
SARSAPARILLA (UNII: 2H1576D5WG) (SARSAPARILLA - UNII:2H1576D5WG)	SARSAPARILLA	30 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
LARREA TRIDENTATA TOP (UNII: PK0TXD049P)	
COMFREY LEAF (UNII: DG4F8T839X)	
CROTON LECHLERI RESIN (UNII: GGG6W25C63)	
EGG SHELL MEMBRANE (UNII: N7QBR4212V)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AHIRAF4M)	
SILVER (UNII: 3M4G523W1G)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
POLYETHYLENE GLYCOL 700 (UNII: 762678AC5R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBIC ACID (UNII: X045WJ989B)	
PHYTOLACCA AMERICANA FRUIT (UNII: WE63661499)	
PHYTOLACCA AMERICANA ROOT (UNII: 11E6V18VEG)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
ST. JOHN'S WORT (UNII: UFH8805FKA)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
WHEY (UNII: 8617Z5FMF6)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:449 11-0134-1	30 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/31/2014	

Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(449 11-0134) , api manufacture(449 11-0134) , label(449 11-0134) , pack(449 11-0134)

Revised: 12/2014

Energique, Inc.