

**MUSCLE/TENDON PAIN AND STRESS RELIEF- calendula officinalis, croton tiglium, natrum 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.*

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**DRUG FACTS:**

**ACTIVE INGREDIENTS:**

Calendula Officinalis 12X, Croton Tiglium 30X, Natrum Muriaticum 30X, Plantago Major 30X, Rhus Tox 30X, Sarsaparilla (Smilax Regelii) 30X.

**INDICATIONS:**

May temporarily relieve pain due to inflammation caused by but not limited to the following: cramping and spasms, pulls and tears, stress and strains.\*\*

\*\*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.

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## **INACTIVE INGREDIENTS:**

Aloe Barbadensis Leaf Juice (Aloe Vera 10X Concentrate), Arnica Montana (Flower)\*, Larrea Tridentata (Leaf)\*, Symphytum Officinale (Leaf)\*, Croton Lechleri (Sap), 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, Salix Alba (Bark)\*, Achillea 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

### **MUSCLE/TENDON**

### **PAIN & STRESS**

### **RELIEF**

Topical Spray

1 fl. oz. (30 ml)

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LOT: XXXXX



**HOMEOPATHIC REMEDY**

**MUSCLE/TENDON PAIN & STRESS 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 Barbadosensis Leaf Juice, Arnica Flower\*, Chaparral Leaf\*, Comfrey Leaf\*, Dragon's Blood Croton Sap, 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\*, Tocopherols (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.

**MUSCLE/TENDON PAIN AND STRESS RELIEF**

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

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:44911-0303
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>CALENDULA OFFICINALIS FLOWERING TOP</b> (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	12 [hp_X] in 1 mL
<b>CROTON TIGLIUM SEED</b> (UNII: 0HK2GZK66E) (CROTON TIGLIUM SEED - UNII:0HK2GZK66E)	CROTON TIGLIUM SEED	30 [hp_X] in 1 mL
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	30 [hp_X] in 1 mL
<b>PLANTAGO MAJOR WHOLE</b> (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII:W2469WNO6U)	PLANTAGO MAJOR WHOLE	30 [hp_X] in 1 mL
<b>TOXICODENDRON PUBESCENS LEAF</b> (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	30 [hp_X] in 1 mL
<b>SMILAX ORNATA ROOT</b> (UNII: 2H1576D5WG) (SARSAPARILLA - UNII:2H1576D5WG)	SMILAX ORNATA ROOT	30 [hp_X] in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>LARREA TRIDENTATA TOP</b> (UNII: PK0TXD049P)	
<b>COMFREY LEAF</b> (UNII: DG4F8T839X)	
<b>CROTON LEHLERI RESIN</b> (UNII: GGG6W25C63)	
<b>LAVANDULA ANGUSTIFOLIA FLOWER</b> (UNII: 19AH1RAF4M)	

<b>SILVER</b> (UNII: 3M4G523W1G)
<b>MELISSA OFFICINALIS LEAF</b> (UNII: 50D2ZE9219)
<b>POLYETHYLENE GLYCOL 1500</b> (UNII: 1212Z7S33A)
<b>PEG-8 DIMETHICONE</b> (UNII: GIA7T7640D)
<b>POLYETHYLENE GLYCOL 700</b> (UNII: 762678AC5R)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>SORBIC ACID</b> (UNII: X045WJ989B)
<b>PHYTOLACCA AMERICANA FRUIT</b> (UNII: WE63661499)
<b>PHYTOLACCA AMERICANA ROOT</b> (UNII: 11E6V18VEG)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)
<b>HYPERICUM PERFORATUM</b> (UNII: XK4IUX8MNB)
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)
<b>WHEY</b> (UNII: 8617Z5FMF6)
<b>SALIX ALBA BARK</b> (UNII: 205MXS71H7)
<b>ACHILLEA MILLEFOLIUM FLOWER</b> (UNII: YQR8R0SQEA)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44911-0303-1	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/18/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/18/2015	

**Labeler** - Energique, Inc. (789886132)

**Registrant** - Apotheca Company (844330915)

### Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(44911-0303) , api manufacture(44911-0303) , label(44911-0303) , pack(44911-0303)