

OSTEOTONE- symphytum officinale, calcarea carbonica, calcarea fluorica, calcarea phosphorica, causticum, hekla lava, pulsatilla (pratensis), rhus tox, silicea, strontium carbonicum liquid
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): 10% of Calcarea Carbonica 12X, Calcarea Fluorica 12X, Calcarea Phosphorica 12X, Causticum 12X, Hekla Lava 12X, Pulsatilla (Pratensis) 12X, Rhus Tox 12X, Silicea 12X, Strontium Carbonicum 12X, Symphytum Officinale 3X.

INDICATIONS:

May temporarily relieve pain in joints and bones and low back pain.**

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

WARNINGS:

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, 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. In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

Adults and children 5 to 10 drops orally, 3 times daily or as otherwise directed by a health care professional. If symptoms persist for more than 7 days, consult your health care professional. Consult a physician for use in children under 12 years of age.

INDICATIONS:

May temporarily relieve pain in joints and bones and low back pain.**

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

FDA evaluated.

INACTIVE INGREDIENTS:

Demineralized water, 20% Ethanol.

QUESTIONS:

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

PACKAGE LABEL DISPLAY:

ENERGIQUE
SINCE 1987
HOMEOPATHIC REMEDY
OSTEOTONE
1 fl. oz. (30 ml)

WARNINGS: If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, 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.

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HOMEOPATHIC REMEDY

OSTEOTONE™

1 fl. oz. (30 ml) 20% Ethanol

Active Ingredients (in each drop):
10% of Calcarea Carbonica 12X, Calcarea Fluorica 12X, Calcarea Phosphorica 12X, Causticum 12X, Hekla Lava 12X, Pulsatilla 12X, Rhus Tox 12X, Silicea 12X, Strontium Carbonicum 12X, Symphytum Officinale 6X.

Inactive Ingredients:
Demineralized water, 20% Ethanol.

DIRECTIONS: Adults and children 5 to 10 drops orally, 3 times daily or as otherwise directed by a health care professional. If symptoms persist for more than 7 days, consult your health care professional. Consult a physician for use in children under 12 years of age.

LOT: XXXXXX

OSTEOTONE

symphytum officinale, calcarea carbonica, calcarea fluorica, calcarea phosphorica, causticum, hekla lava, pulsatilla (pratensis), rhus tox, silicea, strontium carbonicum liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44911-0447
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	6 [hp_X] in 1 mL
OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	12 [hp_X] in 1 mL
CALCIUM FLUORIDE (UNII: O3B55K4YKI) (FLUORIDE ION - UNII:Q80VPU408O)	CALCIUM FLUORIDE	12 [hp_X] in 1 mL
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	12 [hp_X] in 1 mL
CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)	CAUSTICUM	12 [hp_X] in 1 mL
HEKLA LAVA (UNII: C21158IIRK) (HEKLA LAVA - UNII:C21158IIRK)	HEKLA LAVA	12 [hp_X] in 1 mL
PULSATILLA PRATENSIS WHOLE (UNII: 8E272251DI) (PULSATILLA PRATENSIS WHOLE - UNII:8E272251DI)	PULSATILLA PRATENSIS WHOLE	12 [hp_X] in 1 mL
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	12 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	12 [hp_X] in 1 mL
STRONTIUM CARBONATE (UNII: 41YPU4MMCA) (STRONTIUM CATION - UNII:37077S2C93)	STRONTIUM CARBONATE	12 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44911-0447-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	11/29/2017	08/01/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/29/2017	08/01/2024

Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(44911-0447) , api manufacture(44911-0447) , label(44911-0447) , pack(44911-0447)

