

OTOFLAM HP- belladonna, conium maculatum, dulcamara, ferrum phosphoricum, hepar sulphuris calcareum, kali bichromicum, mercurius solubilis, pulsatilla (pratensis), silicea, chamomilla. 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 Belladonna 30X, Chamomilla 30C, Conium Maculatum 30X, Dulcamara 30X, Ferrum Phosphoricum 30X, Hepar Sulphuris Calcareum 30X, Kali Bichromicum 30X, Mercurius Solubilis 30X, Pulsatilla 30X, Silicea 30X.

INDICATIONS:

May temporarily relieve ear pain and swelling.**

**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 4 days, consult your health care professional. Consult a physician for use in children under 12 years of age.

INDICATIONS AND USAGE:

May temporarily relieve ear pain and swelling.**

**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

OTOFLAM HP

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

OTOFLAM HP™

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

Active Ingredients (in each drop):
10% of Belladonna 30X, Chamomilla 30C, Conium Maculatum 30X, Dulcamara 30X, Ferrum Phosphoricum 30X, Hepar Sulphuris Calcereum 30X, Kali Bichromicum 30X, Mercurius Solubilis 30X, Pulsatilla 30X, Silicea 30X.

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 4 days, consult your health care professional. Consult a physician for use in children under 12 years of age.

LOT: XXXXXX

OTOFLAM HP

belladonna, conium maculatum, dulcamara, ferrum phosphoricum, hepar sulphuris calcereum, kali bichromicum, mercurius solubilis, pulsatilla (pratensis), silicea, chamomilla. liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44911-0513
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATROPA BELLADONNA WHOLE (UNII: DSV74G1P2J) (ATROPA BELLADONNA WHOLE - UNII:DSV74G1P2J)	ATROPA BELLADONNA WHOLE	30 [hp_X] in 1 mL
CONIUM MACULATUM FLOWERING TOP (UNII: Q28R5GF371) (CONIUM MACULATUM FLOWERING TOP - UNII:Q28R5GF371)	CONIUM MACULATUM FLOWERING TOP	30 [hp_X] in 1 mL
SOLANUM DULCAMARA TOP (UNII: KPS1B1162N) (SOLANUM DULCAMARA TOP - UNII:KPS1B1162N)	SOLANUM DULCAMARA TOP	30 [hp_X] in 1 mL
FERROSO FERRIC PHOSPHATE (UNII: 91GQH8I5F7) (FERROSO FERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERROSO FERRIC PHOSPHATE	30 [hp_X] in 1 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	30 [hp_X] in 1 mL
POTASSIUM DICHROMATE (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V)	POTASSIUM DICHROMATE	30 [hp_X] in 1 mL
MERCURIUS SOLUBILIS (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	30 [hp_X] in 1 mL
ANEMONE PRATENSIS (UNII: 8E272251DI) (ANEMONE PRATENSIS - UNII:8E272251DI)	ANEMONE PRATENSIS	30 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	30 [hp_X] in 1 mL
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	30 [hp_C] 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:44911-0513-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	10/03/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/03/2019	

Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(44911-0513) , api manufacture(44911-0513) , label(44911-0513) , pack(44911-0513)

Revised: 9/2021

Energique, Inc.