

OTOFLAM HP- belladonna, conium maculatum, dulcamara, hepar sulphuris calcareum, kali bichromicum, mercurius solubilis, pulsatilla (vulgaris), silicea, chamomilla liquid
BioActive Nutritional, 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:

Belladonna 30X, Conium Maculatum 30X, Dulcamara 30X, Hepar Sulphuris Calcareum 30X, Kali Bichromicum 30X, Mercurius Solubilis 30X, Pulsatilla 30X, Silicea 30X, Chamomilla 30C.

INDICATIONS:

For temporary relief of symptoms due to inflammation of the ear.

WARNINGS:

If pregnant or breast-feeding, ask a health care 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:

10 drops orally, 3 times a day. Consult a physician for use in children under 12 years of age.

DIRECTIONS:

10 drops orally, 3 times a day. Consult a physician for use in children under 12 years of age.

INDICATIONS:

For temporary relief of symptoms due to inflammation of the ear.

INACTIVE INGREDIENTS:

Demineralized Water, 25% Ethanol.

QUESTIONS:

Distributed by:
BioActive Nutritional, Inc.
1803 N. Wickham Rd.
Melbourne, FL 32935
bioactivenutritional.com

PACKAGE LABEL DISPLAY:

BIOActive Nutritional

OTOFLAM HP

HOMEOPATHIC

1 FL OZ (30 ml)



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LOT:

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OTOFLAM-HP

HOMEOPATHIC

ACTIVE INGREDIENTS:

Belladonna 30X, Conium Maculatum 30X, Dulcamara 30X, Hepar Sulphuris Calcereum 30X, Kali Bichromicum 30X, Mercurius Solubilis 30X, Pulsatilla 30X, Silicea 30X, Chamomilla 30C.

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0034
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	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
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
PULSATILLA VULGARIS (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	PULSATILLA VULGARIS	30 [hp_X] in 1 mL

SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	30 [hp_A] in 1 mL
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	30 [hp_C] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43857-0034-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	04/04/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/13/2012	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0034) , api manufacture(43857-0034) , label(43857-0034) , pack(43857-0034)

Revised: 4/2017

BioActive Nutritional, Inc.