

TEETHING- arnica montana, trifolium pratense, calcarea carbonica, calcarea fluorica, calcarea phosphorica, chamomilla, kreosotum, silicea 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:

Arnica Montana 3X, Trifolium Pratense 3X, Calcarea Carbonica 12X, Calcarea Fluorica 12X, Calcarea Phosphorica 12X, Chamomilla 12X, Kreosotum 12X, Silicea 12X

INDICATIONS:

For temporary relief of pain due to teething and delayed teething.

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 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:

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

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For temporary relief of pain due to teething and delayed teething.

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

TEETHING

HOMEOPATHIC

1 FL OZ (30 ml)



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LOT:

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TEETHING

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0406
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	3 [hp_X] in 1 mL
TRIFOLIUM PRATENSE FLOWER (UNII: 4JS0838828) (TRIFOLIUM PRATENSE FLOWER - UNII:4JS0838828)	TRIFOLIUM PRATENSE FLOWER	3 [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
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	12 [hp_X] in 1 mL
WOOD CREOSOTE (UNII: 3JYG22FD73) (WOOD CREOSOTE - UNII:3JYG22FD73)	WOOD CREOSOTE	12 [hp_X] in 1 mL

SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)

SILICON DIOXIDE

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:43857-0406-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	07/27/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/27/2016	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0406) , api manufacture(43857-0406) , label(43857-0406) , pack(43857-0406)

Revised: 7/2016

BioActive Nutritional, Inc.