

TEETHING-HP- borax, calcarea carbonica, calcarea phosphorica, chamomilla, passiflora incarnata, podophyllum, 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:

Borax 30X, Calcarea Carbonica 30X, Calcarea Phosphorica 30X, Chamomilla 30X, Passiflora Incarnata 30X, Podophyllum Peltatum 30X, Silicea 30X.

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

PACKAGE LABEL DISPLAY:

BIOActive Nutritional

TEETHING-HP

HOMEOPATHIC

1 FL OZ (30 ml)



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LOT:

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BioActive Nutritional, Inc.
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bioactivenutritional.com

TEETHING-HP

HOMEOPATHIC

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0447
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM BORATE (UNII: 91MBZ8H3QO) (BORATE ION - UNII:440AE30D22)	SODIUM BORATE	30 [hp_X] in 1 mL
OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	30 [hp_X] in 1 mL
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	30 [hp_X] in 1 mL
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	30 [hp_X] in 1 mL
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	PASSIFLORA INCARNATA FLOWERING TOP	30 [hp_X] in 1 mL
PODOPHYLLUM (UNII: 2S713A4VP3) (PODOPHYLLUM - UNII:2S713A4VP3)	PODOPHYLLUM	30 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ET1776YBU4) (SILICON DIOXIDE - UNII:ET1776YBU4)	SILICON DIOXIDE	30 [hp_X]

SILICON DIOXIDE (UNII: E1J7Z0XB04) (SILICON DIOXIDE - UNII:E1J7Z0XB04)		SILICON DIOXIDE	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:43857-0447-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	06/16/2017	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic			06/16/2017	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0447, 43857-0447) , api manufacture(43857-0447) , pack(43857-0447)

Revised: 6/2017

BioActive Nutritional, Inc.