BABY TEETHING- agaicus muscarius, calcarea carbonica, calcarea fluorica, calcarea phosphorica, chamomilla, ferrum phosphoricum, hepar sulphuris calcareum, magnesia phosphorica, phytolacca decandra, podophyllum peltatum, rheum, zincum metallicum liquid King Bio 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.

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## **Baby Teething**

## **HPUS Active Ingredients**

Agaicus muscarius, Calcarea carbonica, Calcarea fluorica, Calcarea phosphorica, Chamomilla, Ferrum phosphoricum, Hepar sulphuris calcareum, Magnesia phosphorica, Phytolacca decandra, Podophyllum peltatum, Rheum, Zincum metallicum

Equal volumes of each in 30X, 60X, and 1LM potencies.

## Purpose

HPUS Ingredient:	Purpose:
Agaicus muscariusir	ritated gums
Calcarea carbonicasl	eeplessness, difficult, delayed teething
Calcarea fluoricato	oothache, vomiting in infants, supports dental development
Calcarea phosphorica	liscomforts from teething
Chamo millade	sire to be held constantly
Ferrum phosphoricum	fever-like disturbaces
Hepar sulphuris calcareum	.overly sensitive
Magnesia phosphorica	complaints of teething
Phytolacca decandra	excess saliva, teething children, clenched teeth
Podophyllum peltatum	drooling, difficult dentition, fussiness, restlessness
Rheuminc	reased saliva, difficult teething, restlessness, irritability
Zincum metallicum	lifficult teething, irritability

#### Uses

for temporary relief of:

- tething pain
- irritated gums
- delayed teething
- fever-like disturbances
- restlessness
- heavy salivation and drooling
- irritability
- desire to be held constantly

#### **Directions**

- Initially, depress pump until primed.
- Spray one dose directly into mouth

**Under 3 months:** Consult a licensed healthcare professional before using

**3 months to 2 years:** 1 spray every 15 minutes. up to 4 doses, then hourly until relieved

**2 to 6 years:** 2 sprays every 15 minutes, up to 4 doses, then hourly until relieved

#### **Warnings**

- **Stop use and ask a doctor,** If symptoms persist or worsen.
- **IIf pregnant or breast-feeding, lask** a healthcare professional before use.
- IKeep out of reach of children

#### Other Information

- This product is intended to compliment, not replace, standard medical care.
- Tamper resistant for your protection. Use only if safety seal is intact.

### **Inactive Ingredients**

Bio-Energetically Enhanced pure water, Carya ovata bark extract (hickory), citrus extract, Lonicer japonica (honeysuckle), polylysine (natural ferment), steviol glycosides (stevia)



#### BABY TEETHING

agaicus muscarius, calcarea carbonica, calcarea fluorica, calcarea phosphorica, chamomilla, ferrum phosphoricum, hepar sulphuris calcareum, magnesia phosphorica, phytolacca decandra, podophyllum peltatum, rheum, zincum metallicum liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57955-0467
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
<b>AMANITA MUSCARIA FRUITING BODY</b> (UNII: DIF093I037) (AMANITA MUSCARIA FRUITING BODY - UNII:DIF093I037)	AMANITA MUSCARIA FRUITING BODY	30 [hp_X] in 59 mL		
<b>OYSTER SHELL CALCIUM CARBONATE, CRUDE</b> (UNII: 2E32821G61) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G61)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	30 [hp_X] in 59 mL		
CALCIUM FLUORIDE (UNII: O3B55K4YKI) (FLUORIDE ION - UNII:Q80VPU408O)	CALCIUM FLUORIDE	30 [hp_X] in 59 mL		
<b>TRIBASIC CALCIUM PHO SPHATE</b> (UNII: 91D9GV0Z28) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	30 [hp_X] in 59 mL		
$ \begin{tabular}{ll} \textbf{MATRICARIA CHAMOMILLA} & (UNII: G0R4UB12ZZ) & (MATRICARIA CHAMOMILLA-UNII: G0R4UB12ZZ) \\ \end{tabular} $	MATRICARIA CHAMOMILLA	30 [hp_X] in 59 mL		
<b>FERROSOFERRIC PHOSPHATE</b> (UNII: 91GQH815F7) (FERROSOFERRIC PHOSPHATE - UNII: 91GQH815F7)	FERROSOFERRIC PHOSPHATE	30 [hp_X] in 59 mL		
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	30 [hp_X] in 59 mL		
MAGNESIUM PHO SPHATE, DIBASIC TRIHYDRATE (UNII: HF539 G9 L3Q) (MAGNESIUM CATION - UNII: T6 V3LHY838)	MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE	30 [hp_X] in 59 mL		
<b>PHYTOLACCA AMERICANA ROOT</b> (UNII: 11E6 VI8 VEG) (PHYTOLACCA AMERICANA ROOT - UNII: 11E6 VI8 VEG)	PHYTOLACCA AMERICANA ROOT	30 [hp_X] in 59 mL		
PODOPHYLLUM (UNII: 2S713A4VP3) (PODOPHYLLUM - UNII:2S713A4VP3)	PODOPHYLLUM	30 [hp_X] in 59 mL		
RHEUM OFFICINALE ROOT (UNII: A47JP5ZG9M) (RHEUM OFFICINALE ROOT - UNII: A47JP5ZG9M)	RHEUM OFFICINALE ROOT	30 [hp_X] in 59 mL		
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	30 [hp_X] in 59 mL		

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
CARYA O VATA BARK (UNII: X765CF609L)			
CITRUS BIOFLAVONOIDS (UNII: BD70459150)			
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)			
POLYEPSILON-LYSINE (4000 MW) (UNII: WB0M8 X4TWR)			
REBAUDIO SIDE A (UNII: B3FUD0528F)			

1	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57955-0467-	1 in 1 CARTON	03/05/2018	
1		59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/05/2018	

# Labeler - King Bio Inc (617901350)

## Registrant - King Bio Inc (617901350)

Establishment				
Name	Address	ID/FEI	Business Operations	
King Bio Inc		6 179 0 1350	manufacture(57955-0467)	

Revised: 3/2018 King Bio Inc