

TMJ / JAW FORMULA- baptisia tinctoria, calcarea fluorica, causticum, hepar sulphuris calcareum, hypericum perforatum, ignatia amara, kalmia latifolia, nux vomica, phytolacca decandra, rhus toxicodendron sanguinaria canadensis, symphytum officinale 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.

TMJ / Jaw Formula™

Drug Facts

HPUS active ingredients: Baptisia tinctoria, Calcarea fluorica, Causticum, Hepar sulphuris calcareum, Hypericum perforatum, Ignatia amara, Kalmia latifolia, Nux vomica, Phytolacca decandra, Rhus toxicodendron, Sanguinaria canadensis, Symphytum officinale. Equal volumes of each ingredient in 10X, 30X, and LM1 potencies.

Uses for temporary relief of: facial pains of the jaw, facial neuralgia, rigid jaw muscles, inflammation in the jaw, clenching of the jaw, cracking sounds.

Inactive Ingredients:

Bio-Energetically Enhanced™ pure water, citric acid and potassium sorbate.

Warnings

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

Directions

- Initially, depress pump until primed.
- Spray one dose directly into mouth.
- **Ages 12 and up: 3 sprays 3 times per day.**
- **Ages 2-12: 2 sprays 3 times per day**

Tamper resistant for your protection. Use only if safety seal is intact.

Uses for temporary relief of:

- facial pains of the jaw
- facial neuralgia
- rigid jaw muscles
- inflammation in the jaw
- clenching of the jaw
- cracking sounds

The image shows the front of a product box for TMJ / Jaw Formula. The box is primarily blue and white. At the top, it lists the NDC number (57955-5032-7) and identifies it as a homeopathic product. The product name 'TMJ / Jaw Formula™' is prominently displayed in large, bold, black letters. Below the name, it says 'Dr. King's NATURAL MEDICINE'. The volume '2 fl oz (59 mL)' is printed at the bottom. On the left side, there is a 'Drug Facts (continued)' section with 'Directions' and a table for dosing. The 'Directions' section includes instructions for initial use and a table with two rows: 'Ages 12 and up' with '3 sprays 3 times per day', and 'Ages 2-12' with '2 sprays 3 times per day'. Below the directions is a tamper-resistant seal warning and contact information for King Bio, Inc. A barcode is located at the bottom left. On the right side, there is another 'Drug Facts' section with 'HPUS active ingredients', 'Uses', 'Inactive ingredients', and 'Warnings'. The 'Warnings' section includes the same three bullet points as seen in the text above: stop use if symptoms worsen, ask a professional if pregnant or breastfeeding, and keep out of reach of children.

Drug Facts (continued)	
Directions	
Initially, depress pump until primed	
Spray one dose directly into mouth.	
Ages 12 and up	3 sprays 3 times per day
Ages 2-12	2 sprays 3 times per day

Drug Facts	
HPUS active ingredients: Baptisia, Calc fluor, Causticum, Hepar sulph calc, Hypericum, Ignatia, Kalmia, Nuxvom, Phytolacca, Rhus tox, Sanguinaria, Symphytum. Equal volumes of each ingredient in 10X, 30X, LM1 potencies.	
Uses for temporary relief of: facial pains of the jaw, facial neuralgia, rigid jaw muscles, inflammation in the jaw, clenching of the jaw, cracking sounds.	
Inactive ingredients: Bio-Energetically Enhanced™ pure water, citric acid, potassium sorbate.	
Warnings	
Stop use and ask a doctor, if symptoms persist or worsen.	
If pregnant or breast-feeding, ask a healthcare professional before use.	
Keep out of reach of children.	

TMJ / JAW FORMULA

baptisia tinctoria, calcarea fluorica, causticum, hepar sulphuris calcareum, hypericum perforatum, ignatia amara, kalmia latifolia, nux vomica, phytolacca decandra, rhus toxicodendron sanguinaria canadensis, symphytum officinale liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57955-5032
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BAPTISIA TINCTORIA ROOT (UNII: 5EF0HWI5WU) (BAPTISIA TINCTORIA ROOT - UNII:5EF0HWI5WU)	BAPTISIA TINCTORIA ROOT	10 [hp_X] in 59 mL
CALCIUM FLUORIDE (UNII: O3B55K4YK) (FLUORIDE ION - UNII:Q80VPU408O)	CALCIUM FLUORIDE	10 [hp_X] in 59 mL
CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)	CAUSTICUM	10 [hp_X] in 59 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	10 [hp_X] in 59 mL
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	10 [hp_X] in 59 mL
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	10 [hp_X] in 59 mL
KALMIA LATIFOLIA LEAF (UNII: 79N6542N18) (KALMIA LATIFOLIA LEAF - UNII:79N6542N18)	KALMIA LATIFOLIA LEAF	10 [hp_X] in 59 mL
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	10 [hp_X] in 59 mL
PHYTOLACCA AMERICANA ROOT (UNII: 11E6V18VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6V18VEG)	PHYTOLACCA AMERICANA ROOT	10 [hp_X] in 59 mL
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	10 [hp_X] in 59 mL
SANGUINARIA CANADENSIS ROOT (UNII: N9288CD508) (SANGUINARIA CANADENSIS ROOT - UNII:N9288CD508)	SANGUINARIA CANADENSIS ROOT	10 [hp_X] in 59 mL
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	10 [hp_X] in 59 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57955-5032-2	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		03/18/2016	

Labeler - King Bio Inc. (617901350)

Registrant - King Bio Inc. (617901350)

Establishment

Name	Address	ID/FEI	Business Operations
King Bio Inc.		617901350	manufacture(57955-5032)

Revised: 3/2016

King Bio Inc.