

COOLING ACUTE PAIN RELIEF- aesculus hippocastanum, arnica montana, bellis perennis, bryonia, calcarea carbonica, calcarea fluorica, cimicifuga racemosa, cobaltum metallicum, gnaphalium polycephalum, hypericum perforatum, kali carbonicum, kali phosphoricum, magnesia phosphorica, oxalicum acidum, phosphorus, rhus toxicodendron, ruta graveolens, zincum metallicum cream

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.

Cooling Acute Pain Relief

Drug Facts

HPUS active ingredients:

Equal volumes of each active ingredient in 10X, 30X and LM1 potencies. Active ingredients 50% of total weight.

Aesculus hippocastanum, Arnica montana, Bellis perennis, Bryonia, Calcarea carbonica, Calcarea fluorica, Cimicifuga racemosa, Cobaltum metallicum, Gnaphalium polycephalum, Hypericum perforatum, Kali carbonicum, Kali phosphoricum, Magnesia phosphorica, Oxalicum acidum, Phosphorus, Rhus toxicodendron, Ruta graveolens, Zincum metallicum.

Uses: for temporary relief of symptoms: •back and neck pain •muscle and joint pain •muscle cramps and stiffness •inflamed muscles and joints •muscle tension and soreness •body aches •tired legs and feet •stiff and swollen joints

Warnings:

- **For external use only.** Avoid contact with eyes and broken skin.
- **Stop use and ask a doctor if** •symptoms worsen or do not improve within 7 days. •skin irritation, redness or rash occurs.
- **Nursing mothers should not apply to breast area.**
- **Keep out of reach of children.**
- **If swallowed,** get medical help or contact a Poison Control Center immediately.

- **Keep out of reach of children.**

Directions:

•Shake before using. •Apply generously to affected areas 2 to 3 times daily, or more often as needed. •Massage in thoroughly until absorbed. •For best results, apply immediately after the onset of symptoms. •Reapply after bathing and before bedtime for ongoing relief. •May be used before and after exercise.

Other information:

- To open: unscrew cap, remove tube seal, replace cap.
- Safety sealed for your protection.
- Do not use if tube seal is missing.
- Store at 68-77° (20-25°C).

Inactive ingredients: Cetearyl alcohol, deionized water, glyceryl stearate, jojoba seed oil, menthol, peppermint oil, phenoxyethanol, pomegranate fruit extract, shea butter, sodium lactate, sodium stearoyl lactylate, sweet almond oil, sweet birch oil.

Drug Facts

HPUS active ingredients	Purpose
Equal volumes of each active ingredient in 10X, 30X and LM1 potencies.	
Active ingredients 50% of total weight.	
Aesculus hippocastanum.....	tired legs and feet
Arnica montana.....	sprains
Bellis perennis.....	sore muscles
Bryonia.....	inflammation
Calcarea carbonica.....	back pain
Calcarea fluorica.....	backache

Cimicifuga racemosa.....leg aches
 Cobaltum metallicum.....muscle fatigue
 Gnaphalium polycephalum.....leg cramps
 Hypericum perforatum.....cramps
 Kali carbonicum.....stiff, swollen joints
 Kali phosphoricum.....backache
 Magnesia phosphorica.....muscle cramps
 Oxalicum acidum.....muscle aches
 Phosphorus.....weak joints
 Rhus toxicodendron.....joint pain
 Ruta graveolens.....body aches
 Zincum metallicum.....backache

COOLING ACUTE PAIN RELIEF

aeculus hippocastanum, arnica montana, bellis perennis, bryonia, calcarea carbonica, calcarea fluorica, cimicifuga racemosa, cobaltum metallicum, gnaphalium polycephalum, hypericum perforatum, kali carbonicum, kali phosphoricum, magnesia phosphorica, oxalicum acidum, phosphorus, rhus toxicodendron, ruta graveolens, zincum metallicum cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57955-4001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HORSE CHESTNUT (UNII: 3C18L6RJAZ) (HORSE CHESTNUT - UNII:3C18L6RJAZ)	HORSE CHESTNUT	10 [hp_X]	in 85 g
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	10 [hp_X]	in 85 g
BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	10 [hp_X]	in 85 g
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT -	BRYONIA ALBA ROOT	10 [hp_X]	

UNII:T7J046Y2B)	POTASSIUM ALBINOSE	in 85 g
OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	10 [hp_X] in 85 g
CALCIUM FLUORIDE (UNII: O3B55K4YKI) (FLUORIDE ION - UNII:Q80VPU408O)	CALCIUM FLUORIDE	10 [hp_X] in 85 g
BLACK COHOSH (UNII: K73E24S6X9) (BLACK COHOSH - UNII:K73E24S6X9)	BLACK COHOSH	10 [hp_X] in 85 g
COBALT (UNII: 3G0H8C9362) (COBALT - UNII:3G0H8C9362)	COBALT	10 [hp_X] in 85 g
PSEUDOGNAPHALIUM OBTUSIFOLIUM (UNII: 36XQ854NWW) (PSEUDOGNAPHALIUM OBTUSIFOLIUM - UNII:36XQ854NWW)	PSEUDOGNAPHALIUM OBTUSIFOLIUM	10 [hp_X] in 85 g
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	10 [hp_X] in 85 g
POTASSIUM CARBONATE (UNII: BQN1B9B9HA) (CARBONATE ION - UNII:7UJQ5OPE7D)	POTASSIUM CARBONATE	10 [hp_X] in 85 g
POTASSIUM PHOSPHATE, DIBASIC (UNII: CI71S98N1Z) (PHOSPHATE ION - UNII:NK08V8K8HR)	POTASSIUM PHOSPHATE, DIBASIC	10 [hp_X] in 85 g
MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE (UNII: HF539G9L3Q) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE	10 [hp_X] in 85 g
OXALIC ACID DIHYDRATE (UNII: 0K2L2U59O) (OXALIC ACID - UNII:9E7R5L6HB1)	OXALIC ACID DIHYDRATE	10 [hp_X] in 85 g
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	10 [hp_X] in 85 g
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	10 [hp_X] in 85 g
RUTA GRAVEOLENS FLOWERING TOP (UNII: N94C2U587S) (RUTA GRAVEOLENS FLOWERING TOP - UNII:N94C2U587S)	RUTA GRAVEOLENS FLOWERING TOP	10 [hp_X] in 85 g
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	10 [hp_X] in 85 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WATER (UNII: 059QF0K00R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
JOJOBA OIL (UNII: 724GKU717M)	
MENTHOL (UNII: L7T10EIP3A)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POMEGRANATE (UNII: 56687D1Z4D)	
SHEA BUTTER (UNII: K49155WL9Y)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
ALMOND OIL (UNII: 66YXD4DKO9)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57955-4001-3	1 in 1 CARTON	02/20/2018	
1		85 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		02/20/2018	

Labeler - King Bio Inc. (617901350)

Registrant - King Bio Inc. (617901350)

Establishment

Name	Address	ID/FEI	Business Operations
King Bio Inc		617901350	api manufacture(57955-4001)

