

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

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.

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

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 stearyl lactate, sweet almond oil, sweet birch oil.

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

PURE HOMEOPATHIC CREAM



NDC# 57955-7302-3

Cooling Acute Pain Relief™

Back & Neck Pain

Muscle & Joint Pain

Cramps & Stiffness

Inflammation

Pain

High Potency Homeopathic Formula
for Professional Use Only

3 oz (85 g)

Keep caution for complete drug facts and product information.

This product has not been clinically tested. Homeopathic provings for each HPLUS ingredient are found in various materia medica referenced in the FDA Compliance Policy Guide. 885528

Drug Facts

HPLUS active ingredients Aesculus hipp, Arnica, Bellis, Bryonia, Calc carb, Calc fluor, Cimicifuga, Cobaltum met, Gnaphalium poly, Hypericum, Kali carb, Kali phos, Mag phos, Oxalicum ac, Phos, Rhus tox, Ruta, Zinc met. Equal volumes of each active ingredient in 10X, 30X and LM1 potencies. Active ingredients 50% of total weight.

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*2112012

COOLING ACUTE PAIN RELIEF

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57955-7302
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 - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	10 [hp_X] 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
O XALIC ACID DIHYDRATE (UNII: 0K2L2U59O) (O XALIC ACID - UNII:9E7R5L6H31)	O XALIC 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: 059QF0KO0R)	
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:57955-7302-3	85 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		02/19/2014	

Labeler - King Bio Inc. (617901350)

Registrant - King Bio Inc. (617901350)

Establishment

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.		002290302	api manufacture(57955-7302)

Revised: 9/2014

King Bio Inc.