ARNICA GEL- arnica montana gel 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.

Arnica Gel

Drug

Facts

Active ingredient:

Arnica montana 1X HPUS*-7%

*HPUS indicates inclusion in the official Homeopathic Pharmacopoeia of the United States.

Uses Temporarily relieves: •swelling form minor injuries •muscle pain and stiffness, •and bruising, due to minor injuries or overexertion. †as per various materia medicas. Product "Uses" have not been evaluated by the FDA. Product has not been clinically tested.

Warnings:

- For external use only. Avoid contact with eyes and broken skin.
- If pregnant or breast-feeding, ask a health professional before use.
- 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.
- Stop use and ask a doctor if: *symptoms worsen or do not improve within 3 days *skin irritation, redness or rash occurs.
- Keep out of reach of children.

Directions: Apply to affected areas 2 or 3 times daily, or more often as needed. For best results, apply at the onset of symptoms.

Other information:

- Do not use if carton or tube seal is broken.
- Store at 68-77°F (20-25°C).
- Keep carton for complete drug facts and product information.

Inactive ingredients: Alcohol denat, carbomer, purified water, sodium hydroxide.

Drug Facts

Active ingredients Purpose†

Arnica montana......Swelling from minor injuries, muscle pain and stiffness, bruising due to minor injuries or overexertion.

*HPUS indicates inclusion in the official Homeopathic Pharmacopoeia of the United States.



ARNICA GEL

arnica montana gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57955-3203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
	ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII: O80TY208ZW)	ARNICA MONTANA	1 [hp_X] in 73 g

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNI: 59TL3WG5CO)		
WATER (UNII: 059QF0KO0R)		
SODIUM HYDRO XIDE (UNII: 55X04QC32I)		

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57955-3203-3	1 in 1 CARTON		
1		73 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
	Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
uı	napproved homeopath	ic	03/07/2016	

Labeler - King Bio Inc. (617901350)

Registrant - King Bio Inc. (617901350)

Establishment				
Name	Address	ID/FEI	Business Operations	
King Bio Inc.		617901350	manufacture(57955-3203)	

Revised: 3/2016 King Bio Inc.