BRAZMEDICS ARNICA CREAM- brazmedics arnica cream cream Homeocare Laboratories

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.

BRAZMEDICS ARNICA Cream

Active Ingredient:

Arnica Montana 1X (HPUS) 7%

Purpose

#1 First-aid Remedy for the relief of Bruises, Injuries, Muscle Aches, Pre/Post Surgery, Pain Relief Homeopathic Medicine

PARABENS FREE

Keep out of the reach of children

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Warnings:

For external use only. Ask a doctor before use if pregnant or breastfeeding. **Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Inactive Ingredients:

Avocado Oil, Caprylyl Glycol, Cetyl Alcohol, Dimethicone, Dimethyl Taurate Copolymer, Glycerin USP, Glyceryl Stearate, Caprylic/Capric Triglyceride, Hexylen Glycol, Phenoxyethanol, Polyethylene, Sodium Polyacrylate, Potassium Sorbate, Purified water, Sodium Acrylate/Sodium Acryloyl, Sunflower Oil

Directions:

For external use only. Apply generously to affected area, 2 to 3 times daily or as needed. Rub gently until complete absorption. Safe for children over 2 year old (under 2 years ask a doctor).

When using this product: Do not get into eyes and do not apply on open skin. **Stop use and ask a doctor if:** Condition worsens, symptoms last more than 7 days, you are allergic to any of the ingredients.

Directions:

For external use only. Apply generously to affected area, 2 to 3 times daily or as needed. Rub gently until complete absorption. Safe for children over 2 years old (under 2 years ask a doctor).

Brazmedics Arnica Front Label



Brazmedics Arnica Cream Back Label

Active Ingredient: Arnica Montana 1X (HPUS) 7%
Inactive Ingredients: Avocado Oil, Caprylyl Glycol,
Cetyl Alcohol, Dimethicone, Dimethyl Taurate Copolymer,
Glycerin USP, Glyceryl Stearate, Caprylic/Capric Triglyceride, Hexylen Glycol, Phenoxyethanol, Polyethylene,
Sodium Polyacrylate, Potassium Sorbate, Purifed water,
Sodium Acrylate/Sodium Acryloyl, Sunflower Oil,
Directions: For external use only. Apply generously to
affected area, 2 to 3 times daily or as needed, Rub gently
until complete absorption. Safe for children over 2 years old
(under 2 years ask a doctor).
Warnings: For external use only. Ask a doctor before
use if pregnant or breastfeeding, Keep out of the
reach of children. If swallowed, get medical help or contact
a Poison Control Center right away.
When using this product: Do not get into eyes and do

When using this product: Do not get into eyes and do not apply on open skin, Stop use and ask a doctor if: Condition worsens, symptoms last more than 7 days, you are all ergic to any of the ingredients.

Manufactured for Brazmedics, LLC Lot 1938 422 East 72nd Street, New York, NY 10021 Exp.11/20



BRAZMEDICS ARNICA CREAM

brazmedics arnica cream cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61727-114	
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 1 [hp_X]	

Inactive Ingredients	
Ingredient Name	Strength
AVOCADO O IL (UNII: 6 VNO72PFC1)	

DIMETHICO NE (UNII: 92RU3N3Y1O)		
SODIUM ACRYLATE/SODIUM ACRYLO YLDIMETHYLTAURATE COPOLYMER (400000 MW) (UNII: 1DXE3F3OZX)		
TRICAPRIN (UNII: O1PB8EU98M)		
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
GLYCERIN (UNII: PDC6A3C0OX)		
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)		
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
WATER (UNII: 059QF0KO0R)		
SODIUM ACRYLATE (UNII: 7C98FKB43H)		
SUNFLOWER OIL (UNII: 3W1JG795YI)		

l	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:61727-114-02	1 [hp_X] in 1 TUBE; Type 0: Not a Combination Product	07/06/2018		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic		07/06/2018		

Labeler - Homeocare Laboratories (088248828)

Registrant - Homeocare Laboratories (088248828)

Establishment				
Name	Address	ID/FEI	Business Operations	
Homeocare Laboratories		088248828	manufacture(61727-114)	

Revised: 7/2018 Homeocare Laboratories