ARNICA CREAM - arnica montana cream
Newton Laboratories, 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 Cream

INDICATIONS & USAGE SECTION

Arnica Cream: Formulated for symptoms associated with trauma, surgery, strains and sprains such as bruising, swelling, pain and stiffness.

DOSAGE & ADMINISTRATION SECTION

Directions: EXTERNAL USE ONLY. Ages 2 and up, apply a thin coating up to four times daily to affected area. Repeat as needed or as directed by your healthcare professional. Under age 2, consult a licensed healthcare professional. Avoid eye contact; if eye contact occurs, rinse with water for at least 15 minutes. If allergic response or irritation occurs or persists, discontinue use and consult a licensed healthcare professional.

OTC - ACTIVE INGREDIENT SECTION

Arnica 60x, Arnica 30x, Arnica 10x, Arnica 3x

OTC - PURPOSE SECTION

Formulated for symptoms associated with trauma, surgery, strains and sprains such as bruising, swelling, pain and stiffness.

INACTIVE INGREDIENT SECTION

Inactive Ingredients: USP Purified Water, Pomace Olive Oil, El Deodorized Cocoa Butter, Beeswax (organic), Jojoba Esters, Soy Lecithin (organic), USP Glycerin, natural (organic, vegetable), USP Gluten-free, non-GMO Cane Alcohol (organic), Grapefruit Seed Extract, Plant preservatives (natural), Gluten-free, non-GMO Xanthan Gum.

QUESTIONS SECTION

www.newtonlabs.net Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30012 Questions? 1.800.448.7256

WARNINGS SECTION

Warning: Do not use if tamper - evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

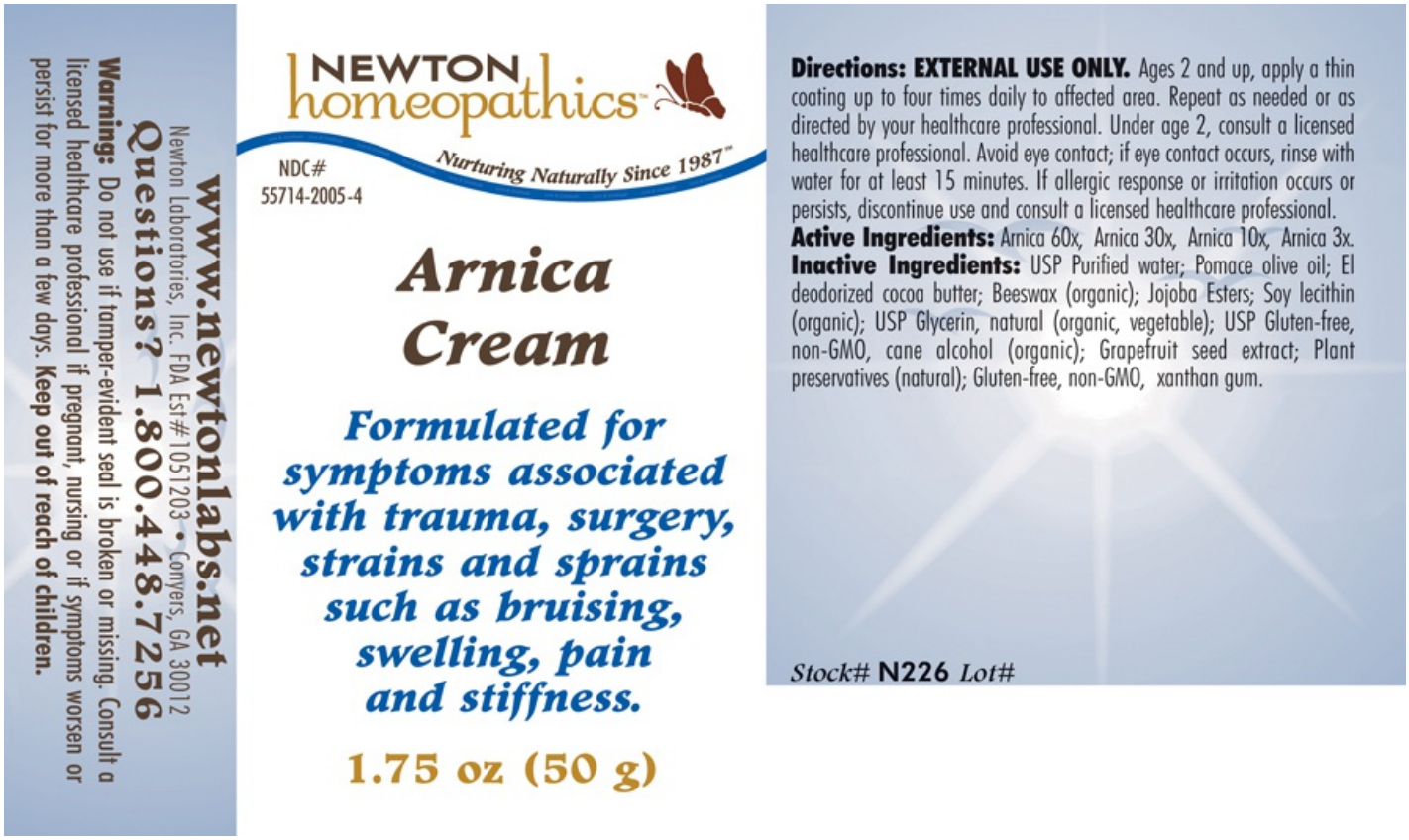
OTC - PREGNANCY OR BREAST FEEDING SECTION

Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

PACKAGE LABEL



ARNICA CREAM

arnica montana cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55714-2005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Arnica Montana (UNII: O80TY208ZW) (Arnica Montana - UNII:O80TY208ZW)	Arnica Montana	60 [hp_X] in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
Olive Oil (UNII: 6UYK2W1W1E)	
Cocoa Butter (UNII: 512OYT1CRR)	

Royal Jelly (UNII: L497I37F0C)	
Jojoba Oil (UNII: 724GKU717M)	
Lecithin, Soybean (UNII: 1DI56QDM62)	
Glycerin (UNII: PDC6A3C0OX)	
Alcohol (UNII: 3K9958V90M)	
Citrus Paradisi Seed (UNII: 12F08874Y7)	
Lonicera Japonica Flower (UNII: 4465L2WS4Y)	
Xanthan Gum (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2005-4	50 g in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/01/2013	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-2005)

Revised: 8/2013 Newton Laboratories, Inc.