

LABOFLEX ARNIPATCH MUSCLE AND JOINT PATCH- arnica montana patch Laboflex, 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.

LABOFLEX Arnipatch Arnica Muscle and Joint Patch

Drug Facts

Active Ingredients

Arnica Montana 1X - 7% HPUS

Purpose

Muscle strain, Bruising

Uses

- * For the temporary relief of muscle pain and stiffness due to minor injuries, overexertion and falls. Reduces pain, swelling and discoloration from bruises.

Warnings

For external use only.

Do not use if you are allergic to Arnica montana or to any of this product's inactive ingredients. Do not use if you are allergic to the dressing or any of its components.

When Using This Product

When using this product ■ Use only as directed ■ Do not bandage tightly ■ Avoid contact with eyes ■ Do not apply to open wounds or damaged skin

Keep Out of Reach of Children

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

Stop and ask doctor if

Stop and ask doctor if ■ Condition worsens ■ Irritation occurs ■ Symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breastfeeding

If pregnant or breastfeeding, ask a health professional before use.

Directions

Adults and children 12 years of age and over

■ Clean and dry affected area ■ Remove patch from film ■ Place healing patch on intact skin ■ Patch may be worn up to 12 hours.

Children under 12 years of age Consult a doctor

Inactive Ingredients

Carboxymethylcellulose Sodium, Dihydroxyaluminum Aminoacetate, Edetate Sodium, Glycerin, Methyl- paraben, Mint Oil, Partially Neutralized Polyacrylic Acid, Polysorbate 80, Povidone-K90, Propylparaben, Propylene Glycol, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Purified Water

Questions or comments?

Call toll-free 1-800-655-0252 or email: wooshinlabo-us@wooshinmed.com

Product Packaging

20mm

Drug Facts

Active ingredient	Purpose
Arnica Montana 1X HPUS 7%*	Muscle strain, Bruising

*The letters "HPUS" indicate that the component in this product is officially monographed in the Homeopathic Pharmacopoeia of the United States.

Uses * For the temporary relief of muscle pain and stiffness due to minor injuries, overexertion and falls. Reduces pain, swelling and discoloration from bruises. Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

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Other information

■ Do not use if pouch is opened or damaged
■ Tightly reseal pouch containing unused patches
■ Store at room temperature
■ Do not freeze

Inactive ingredients

Alcohol, Carboxymethylcellulose sodium, Dihydroxyaluminum aminoacetate, Edetate sodium, Glycerin, Polyacrylic acid, Polysorbate 80, Sodium polyacrylate, Tartaric acid, Titanium dioxide, Water, 1,2-Hexanediol

Questions or comments? Call toll-free 1-800-655-0252 or email: wooshinlabo-us@wooshinmed.com

Sore muscles, bruising, and sprains NDC 83655-101-15
Pain relief

LaboFlex™
ARNIPATCH
Arnica Muscle and Joint Patch
Homeopathic Hydrogel Patch

Natural Pain Relief

- Convenient use
- Easy to apply
- Stretchable
- Lasts up to 12 hours

5 Patches
(3.9" x 4.7"/10cm x 12 cm)

LABOFLEX
Manufactured for
Laboflex INC.
46 Corporate Park, Suite 140
Irvine, CA 92606
Made in Slovenia

1 8685 00004 6



Drug Facts

Active ingredient Arnica Montana 1X HPUS 7%* **Purpose** Muscle strain, Bruising
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LaboFlex™

Sore muscles, bruising, and sprains Pain relief

LaboFlex™

ARNIPATCH

Arnica Muscle and Joint Patch

Homeopathic Hydrogel Patch



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LABOFLEX ARNIPATCH MUSCLE AND JOINT PATCH

arnica montana patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83655-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARNICA MONTANA (UNII: O80TY208Z W) (ARNICA MONTANA - UNII:O80TY208Z W)	ARNICA MONTANA	1 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)
WATER (UNII: 059QF0KO0R)
TARTARIC ACID (UNII: W4888I119H)
ALCOHOL (UNII: 3K9958V90M)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
EDETATE SODIUM (UNII: MP1J8420LU)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83655-101-15	5 g in 1 POUCH; Type 0: Not a Combination Product	09/07/2023	
2	NDC:83655-101-21	5 in 1 CARTON	09/07/2023	
2		5 g in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		09/07/2023	

Labeler - Laboflex, Inc. (128394050)

Registrant - Laboflex, Inc. (128394050)

Establishment

Name	Address	ID/FEI	Business Operations
WOOSHIN LAPACHE d.o.o.		507385209	manufacture(83655-101)

Revised: 12/2023

Laboflex, Inc.