

**NEKVNRO PFERDEBALSAM- arnica montana(arnica) 7%, hamamelis virginiana
(witch hazel) 2.5% pferdebalsam gel
Jiangxi Hemei Pharmaceutical Co., Ltd**

84010-031

Active Ingredient

Arnica Montana (Arnica)7%W/W

Hamamelis Virginiana (Witch Hazel) 2.5%W/W

Purpose

Pain, inflammation

Pain, Fatigue

Use

Natural temporary relief for aches, pains and inflammation from minor injuries, overexertion and fatigue.

Warnings

For external use only.

Do not use on broken skin or open wounds.

Stop and ask a doctor if

Pain Persists for more than 5 days

.If pain, redness, or swelling worsens

.if new symptoms occur

Do not use

Do not use on damaged or broken skin

When Using

When using this product avoid contact with eyes or mucous membranes

Stop Use

.If pain, redness, or swelling worsens

.if new symptoms occur

Ask Doctor

Pain Persists for more than 5 days

.if pain, redness, or swelling worsens

.if new symptoms occur

Keep Out Of Reach Of Children

If swallowed, get medical help or contact a poison control center right away.

Directions

Adults and children over the age of 2 years old: Apply generously with gentle rubbing to the affected area 2-3 times daily or as needed. Children less than 2 years of age: Consult a doctor.

Other information

If pregnant or Breast-feeding, ask a health professional before use.

Inactive ingredients

Alcohol, carbomer, purified water, sodium hydroxide. Vanillyl butyl ether

PRINCIPAL DISPLAY PANEL

| Ingredient Name | Basis of Strength | Strength |
|---|--|--------------------|
| ARNICA MONTANA (UNII: O80TY208Z W) (ARNICA MONTANA - UNII:O80TY208Z W) | ARNICA MONTANA | 7 g in 100 mL |
| HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS) (HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS) | HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK | 2.5 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| VANILLYL BUTYL ETHER (UNII: S2ULN37C9R) | |
| CARBOMER 1342 (UNII: 809Y72KV36) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:84010-031-01 | 220 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/23/2024 | |
| 2 | NDC:84010-031-02 | 300 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/23/2024 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M017 | 09/23/2024 | |

Labeler - Jiangxi Hemei Pharmaceutical Co., Ltd (724892056)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------------|---------|-----------|------------------------|
| Jiangxi Hemei Pharmaceutical Co., Ltd | | 724892056 | manufacture(84010-031) |

Revised: 9/2024

Jiangxi Hemei Pharmaceutical Co., Ltd