

ARNICA PAIN RELIEF- arnica montana gel
United Laboratories Manufacturing, LLC

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 Pain Relief

Drug Facts

Active ingredient

Mountain arnica (Arnica montana) 3X HPUS

The letters 'HPUS' indicate that the component in this product is officially monographed in the Homoeopathic Pharmacopoeia of the United States.

Purpose

Pain reliever

Use

temporarily relieves minor aches and pains associated with sore muscles, joint discomfort, strains, sprains, arthritis, and bruises.

Warnings

For external use only.

Avoid contact with eyes.

Do not use

- on open wounds
- cuts
- damaged skin
- infected skin.

Stop use and ask a doctor if

symptoms persist for more than 7 days or worsens.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 2 years and above:
- Apply a thin layer to affected area and surrounding areas as soon as possible after injury.
- Lightly rub in and reapply after 30 seconds.
- Repeat 4 times a day for 3 to 5 days.
- When pain has subsided, apply once each morning and evening for continued temporary relief.

Other information:

Store tightly closed in a cool, dry place.

Inactive ingredients

Aloe vera leaf juice, benzoic acid, carbomer 940, emu oil, eucalyptus oil, glycerin, PEG-40 hydrogenated castor oil, phenoxyethanol, sodium hydroxide, sorbic acid

Package Labeling:

<p>Drug Facts (continued)</p> <p>Do not use <input type="checkbox"/> on open wounds <input type="checkbox"/> cuts <input type="checkbox"/> damaged skin <input type="checkbox"/> infected skin.</p> <p>Stop use and ask a doctor if symptoms persist for more than 7 days or worsens.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> <input type="checkbox"/> Adults and children 2 years and above: <input type="checkbox"/> Apply a thin layer to affected area and surrounding areas as soon as possible after injury. <input type="checkbox"/> Lightly rub in and reapply after 30 seconds. <input type="checkbox"/> Repeat 4 times a day for 3 to 5 days. <input type="checkbox"/> When pain has subsided, apply once each morning and evening for continued temporary relief. <p>Other information Store tightly closed in a cool, dry place.</p> <p>Inactive ingredients Aloe vera leaf juice, benzoic acid, carbomer 940, emu oil, eucalyptus oil, glycerin, PEG-40 hydrogenated castor oil, phenoxyethanol, sodium hydroxide, sorbic acid</p>		<p>Drug Facts</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 60%;">Active ingredient</td> <td style="width: 40%;">Purpose</td> </tr> <tr> <td>Mountain arnica (<i>Arnica montana</i>) 3X HPUS</td> <td>Pain reliever</td> </tr> </table> <p>The letters 'HPUS' indicate that the component in this product is officially monographed in the Homeopathic Pharmacopoeia of the United States.</p> <p>Use Temporarily relieves minor aches and pains associated with sore muscles, joint discomfort, strains, sprains, arthritis, and bruises.</p> <p>Warnings For external use only. Avoid contact with eyes.</p>	Active ingredient	Purpose	Mountain arnica (<i>Arnica montana</i>) 3X HPUS	Pain reliever
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ARNICA PAIN RELIEF

arnica montana gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62400-0034
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	3 [hp_X] in 113 g

Inactive Ingredients

Ingredient Name	Strength

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
EMU OIL (UNII: 344821WD61)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62400-0034-1	113 g in 1 JAR; Type 0: Not a Combination Product	06/20/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		06/20/2017	

Labeler - United Laboratories Manufacturing, LLC (807878116)

Establishment

Name	Address	ID/FEI	Business Operations
United Laboratories Manufacturing, LLC		807878116	manufacture(62400-0034)

Revised: 11/2022

United Laboratories Manufacturing, LLC