

REAL TIME PAIN RELIEF DAILY RELIEF- arnica montana (2x h.p.u.s.) lotion
Cosmetic Specialty Labs, 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.

Real Time Pain Relief Daily Relief

Active Ingredient

Arnica Montana (2X H.P.U.S.)

*The letters H.P.U.S. indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.

Purpose

Bruising, Stiffness, Pain

Uses:

Temporarily relieves symptoms of muscle pain, soreness, bruising and swelling due to overexertion or injury.

Warnings

for external use only

When using this product

avoid contact with eyes

Warnings and Precautions

If swallowed, get medical help or contact a Poison Control Center immediately. Test for allergy by rubbing small amount on skin first. Do not use if allergic to or hypersensitive to any ingredient. If condition worsens or does not improve consult a doctor.

Stop use and ask a doctor

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present
- irritation develops

Keep all medicines out of reach of children.

Directions

Apply to affected area 2 times daily

- or as needed.

Other Ingredients

Purified Water, Methylsulfonylmethane, Sorbitol, Cetearyl Alcohol, SD Alcohol40, Cetyl Alcohol, Carbomer, Butylene Glycol, Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Emu Oil, Phenoxyethanol, Caprylyl Glycol, Triethanolamine, Glycerin, Myristica Fragrans (Nutmeg) Extract, Fragrance, Diazolidinyl Urea, Salix Alba (Willow) Bark Extract, Aloe Barbadensis Leaf Juice, Menthol, Extracts of: (Calendula officianlis (Marigold), Anthemis nobilis (Roman Chamomile), Tilia cordata (Lime Tree), Centaurea cyanus (Cornflower), Chamomilla recutita (Matricaria Chamomilla), Hypericum perforatum (St. John's Wort)), Coriandrum Sativum (Coriander) Fruit Oil.

Package Label, Principal Display Panel and Drug Facts

\$10

REAL TIME
Pain Relief®

DAILY RELIEF

Topical Lotion

Net Wt. 1.5 Fl. Oz. / 45 mL

PEEL TO OPEN

DRUG FACTS INSIDE

NDC #58133-600-15
Distributed by: RTPR LLC,
Edmond, OK 73003
www.RTPR.com

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9953022

PEEL TO OPEN

Drug Facts continued

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There is no scientific evidence that homeopathic products work. The product's claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts

Drug Facts	
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REAL TIME PAIN RELIEF DAILY RELIEF

arnica montana (2x h.p.u.s.) lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58133-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	2 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
EMU OIL (UNII: 344821WD61)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
MYRISTICA FRAGRANS FRUIT (UNII: GOO22BTU71)	

TILIA CORDATA FLOWER (UNII: CFN6G1F6YK)
CENTAUREA CYANUS FLOWER (UNII: QZ239038YC)
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ)
CORIANDRUM SATIVUM WHOLE (UNII: 740M8BF6EF)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
SORBITOL (UNII: 506T60A25R)
SALIX ALBA BARK (UNII: 205MXS71H7)
CETYL ALCOHOL (UNII: 936JST6JCN)
WATER (UNII: 059QF0K00R)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CARBOMER 934 (UNII: Z135WT9208)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
ALOE (UNII: V5VD430YW9)
MENTHOL (UNII: L7T10EIP3A)
CALENDULA OFFICINALIS SEED OIL (UNII: 9JS8DS42SV)
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)
2,2-DICHLORO-1-(2-CHLOROPHENYL)ETHANOL (UNII: 1O5KW1KM6N)
HAMAMELIS VIRGINIANA LEAF (UNII: T07U1161SV)
CLOPYRALID TRIETHANOLAMINE (UNII: O7T195VRMB)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-300-15	45 mL in 1 TUBE; Type 0: Not a Combination Product	01/31/2014	
2	NDC:58133-300-04	120 mL in 1 TUBE; Type 0: Not a Combination Product	01/31/2014	
3	NDC:58133-300-12	345 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/31/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/31/2014	

Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Registrant - Cosmetic Specialty Labs, Inc. (032973000)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty Labs, Inc.		032973000	manufacture(58133-300)

