RELIEVEIT GEL- arnica montana gel
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.

RelieveIt Gel

Active Ingredient

Arnica montana 1X HPUS: 7%

Purpose

Arthritis • bursitis • Fibromyalgia • Tendonitis • Joint pain/discomfort
- Sciatica • Swelling • Muscle pulls/aches/soreness

Uses:

Arthritis • Osteoarthritis • Backaches • Bursitis •
Fibromyalgia • Tendonitis • Joint pain/discomfort
• Sciatica • Swelling

Warnings:

for external use only

When using this product:

use only as directed • avoid contact with eyes
or mucous membranes • do not apply to open
wounds, damaged, or very sensitive skin • do
not use if you are allergic to Arnica montana or to any of this product's
inactive ingredients • do not apply bandage tightly or use heating pad
Keep out of reach of children.
If swallowed, get medical help or contact the
Poison Control Center right away.

Directions:

Adults and children 2 years and over:
•Shake well before using •Apply a sufficient
amount of RelieveIt® Gel to cover the
affected area • Repeat as needed • After
applying, wash hands with soap and water
Children under 2: consult a doctor

Other ingredients:

Calendula officinalis, Carbomer 934P, Cyclomethicone, Ethyl Alcohol, Eucalyptus, Glycerin, Hydroxypropyl Cellulose, Isopropyl Myristate, Juniper Oil, Laureth-7, Polyacrylamide, Polyethylene Glycol 3350, Polysorbate 80, Propyl Gallate, Propylene Glycol, Purified Water, Resin, Sodium Hydroxide, Sorbic Acid, Wintergreen, and Xanthan Gum.

*These “Uses” have not been evaluated by the Food & Drug Administration.

Stop use and ask a doctor if:

excessive redness or irritation is present •

condition worsens • pain persists for more than

3 days

If pregnant or breast feeding:

ask a health professional before use

Other Information

Do not use if glued carton end flaps are open or if tube seal is broken.

Store at 68-77°F (20-25°C)

Principal Display Panel and Drug Facts

RELIEVEIT GEL

arnica montana gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58133-951
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	7 [hp_M] in 1 g

Inactive Ingredients	
Ingredient Name	Strength
CYCLOMETHICONE (UNII: NMQ347994Z)	
METHYL ALCOHOL (UNII: Y4S76JWI15)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)	
JUNIPER BERRY OIL (UNII: SZH16H44UY)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
BENZOIN RESIN (UNII: GK21SBA74R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PROPYLENE GLYCOL 2-METHYLBUTYRATE (UNII: QH216IX8SV)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
CARBOMER 934 (UNII: Z135WT9208)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
SORBIC ACID (UNII: X045WJ989B)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
AMMONIUM LAURETH-7 SULFATE (UNII: 9LPV636QCV)	
GAULTHERIA PROCUMBENS LEAF (UNII: 2125M16OWN)	
CALENDULA OFFICINALIS SEED OIL (UNII: 9JS8DS42SV)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-951-02	70 g in 1 TUBE; Type 0: Not a Combination Product	10/22/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/22/2018	

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(58133-951)

Revised: 11/2018 Cosmetic Specialty Labs, Inc.