RELIEVEIT SPRAINGO GEL- arnica montana, ruta graveolens, symphytum officinale, mentha piperita (peppermint) 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 SprainGo Gel

Active Ingredient

Arnica montana: 1X – 7%

Ruta graveolens: 2%

Symphytum Officinale (Comfrey root): 2%

Mentha Piperita: 1.25%

Purpose

Significantly reduces swelling and pain associated with acute sprains, strains and muscle overexertion. Reduces discoloration from bruising.

Uses:

Sprains, Strains, Muscle/Tendon Pulls, Tendonitis

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 any of this product's active or inactive ingredients • do not apply bandage tightly or use heating pad • do not resume normal activity without the advice of a

- medical professionall

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® SprainGo 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:

Harpagophytum procumbens, Carbomer 934P, Cyclomethicone, C13/14 Isoparaffin, Ethyl Alcohol, Eucalyptus Oil, Glycerin, Hydroxypropylcellulose, Isopropyl Myristate, Juniper Oil, Laureth-7, Polyacrylamide, Polyethylene Glycol 3350, Polysorbate 80, Propyl Gallate, Propylene Glycol, Purified Water, Resin, Sodium Hydroxide, Sorbic Acid, Wintergreen Oil 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 7 days

If pregnant or breast feeding:

ask a health professional before use

Other Information

Store at 68-77°F (20-25°C)

Principal Display Panel and Drug Facts

RELIEVEIT SPRAINGO GEL

arnica montana, ruta graveolens, symphytum officinale, mentha piperita (peppermint) gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58133-950
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 mL
MENTHA PIPERITA (UNII: 79M2M2UDA9) (MENTHA PIPERITA - UNII:79M2M2UDA9)	MENTHA PIPERITA	7 [hp_M] in 1 mL
SYMPHYTUM OFFICINALE WHOLE (UNII: H8FJJ6KX5Y) (SYMPHYTUM OFFICINALE WHOLE - UNII:H8FJJ6KX5Y)	SYMPHYTUM OFFICINALE WHOLE	2 [hp_M] in 1 mL
RUTA GRAVEOLENS FLOWERING TOP OIL (UNII: VDI0O08XRA) (RUTA GRAVEOLENS FLOWERING TOP OIL - UNII:VDI0O08XRA)	RUTA GRAVEOLENS FLOWERING TOP OIL	2 [hp_M] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE (UNII: NMQ347994Z)	
METHYL ALCOHOL (UNII: Y4S76JWI15)	
GAULTHERIA PROCUMBENS LEAF (UNII: 2125M16OWN)	
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)	
KALANCHOE PINNATA LEAF (UNII: 3R963LO08T)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
HARPAGOPHYTUM PROCUMBENS ROOT (UNII: 1OYM338E89)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-950-02	70 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/17/2018	
2	NDC:58133-950-16	474 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/17/2018	
3	NDC:58133-950-37	3780 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/17/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/17/2018	

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(58133-950)

Revised: 10/2018 Cosmetic Specialty Labs, Inc.