

**RELIEVEIT REGENERATING GEL- arnica montana, calendula officinalis, boswellia serrata, harpagophytum procumbens, kalanchoe pinnata 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 Regenerating Gel

Active Ingredient

Arnica montana 1X: 7%

Calendula officinalis 6X: 2%

Boswellia serrata: 2%

Harpagophytum procumbens(Devil's Claw): 5%

Kalanchoe Pinnata (Wonder of the World): 2%

Purpose

For recovery from muscle aches, fatigue and soreness.

Uses:

- Delayed Onset muscle Soreness (DOMS)
- Acute Muscle soreness • Tendonitis
- Muscle pulls/ aches /soreness/ strains
- Joint pain/ discomfort

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 professional

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® Regenerating 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:

Carbomer 934P, Cyclomethicone, Ethyl Alcohol, Eucalyptus Oil, Glycerin, Hydroxypropyl Cellulose, C13/14 Isoparaffin, 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, 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

Stop Soreness Right Away

Relievelt Regenerating Gel
minimizes the effect of
Delayed and Acute Muscle
Soreness



Promotes Speedy Recovery
Use Before and After
Physical Activities

Contents:

1 pump bottle of Relievelt Regenerating Gel
Net weight - 16 oz(474 ml)



**SHAKE WELL
BEFORE USE**



Relievelt® Regenerating Gel

For best results, apply to all areas of
muscle aches, fatigue and soreness

Drug Facts

Active Ingredients
Arnica montana 1X: 7%
Calendula officinalis 6X: 2%
Boswellia serrata: 2%
Harpagophytum procumbens (Devil's Claw): 5%
Kalanchoe Pinnata (Wonder of the World): 2%

Purpose

For recovery
from muscle
aches, fatigue
and soreness.

Uses*

- Delayed Onset muscle Soreness (DOMS)
- Acute Muscle soreness • Tendonitis
- Muscle pulls / aches /soreness/ strains
- Joint pain/ discomfort

Warnings: For external use only

When using this product:

use only as directed • avoid contact with eyes or with mucous membranes • do not apply to open wounds or to damaged or sensitive skin • do not use if you are allergic to any of this product's active or inactive ingredients • do not bandage tightly or use heating pad

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.

Keep out of reach of children.

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

Directions

Other information: Store at 68-77 °F (20-25 °C)

Adults and children 2 years and over:

- Shake well before using • Apply a sufficient amount of Relievelt® Gel to cover the affected areas • Repeat as needed • After applying, wash hands with soap and water

Children under 2: consult a doctor

Inactive ingredients

Carbomer 934P, Cytomethicone, Ethyl Alcohol, Eucalyptus Oil, Glycerin, Hydroxypropylcellulose, C13/14 Isoparaffin, 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, Xanthan Gum.

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

Manufactured for SprainGo LLC
3802 Spectrum Blvd
Suite 112 E
Tampa, FL 33612
www.2Relievelt.com
Patent Pending
LOT#



RELIEVEIT REGENERATING GEL

arnica montana, calendula officinalis, boswellia serrata, harpagophytum procumbens, kalanchoe pinnata gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58 133-952
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BOSWELLIA SERRATA RESIN OIL (UNII: 5T1XCE6K8K) (BOSWELLIA SERRATA	BOSWELLIA SERRATA	2 [hp_M]

RESIN OIL - UNII:5T1XCE6K8K)	RESIN OIL	in 1 mL
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	7 [hp_M] in 1 mL
KALANCHOE PINNATA LEAF (UNII: 3R963LO08T) (KALANCHOE PINNATA LEAF - UNII:3R963LO08T)	KALANCHOE PINNATA LEAF	2 [hp_M] in 1 mL
HARPAGOPHYTUM PROCUMBENS ROOT (UNII: 1OYM338E89) (HARPAGOPHYTUM PROCUMBENS ROOT - UNII:1OYM338E89)	HARPAGOPHYTUM PROCUMBENS ROOT	5 [hp_M] in 1 mL
CALENDULA OFFICINALIS SEED OIL (UNII: 9JS8DS42SV) (CALENDULA OFFICINALIS SEED OIL - UNII:9JS8DS42SV)	CALENDULA OFFICINALIS SEED OIL	2 [hp_M] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GAULTHERIA PROCUMBENS LEAF (UNII: 2125M16OWN)	
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)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-952-16	474 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/17/2018	
2	NDC:58133-952-37	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(58133-952)

Revised: 10/2018

Cosmetic Specialty Labs, Inc.