

PAIN RELIEF ROLLER SIGNATURE CARE- menthol 4% gel

Better Living

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient	Purpose
Menthol 4%.....	Topical anesthetic

Uses

For the temporary relief from minor aches and pains of soar muscles and joints associated with arthritis, backache, strains and sprains

Warnings

For external use only.

Flammable: Do not use while smoking or near heat or flame

When using this product • avoid contact with eyes or mucouse membranes•do not apply to wounds or damaged skin • do not apply to the irritated skin • do not bandage • wash hands after use with cool water • do not use with heating pad or device.

Stop use and ask a doctor if • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately

Directions

Shake well. Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: consult a doctor.

Inactive ingredients

Aloe Barbadensis Leaf Extract
Arctium Lappa Root (Burdock) Extract
Arnica Montana Flower Extract
Boswellia Carterii Resin Extract
Calendula Officinalis Extract
Camellia Sinensis Leaf Extract
Camphor
Carbomer
FD&C Blue #1
FD&C Yellow #5
Glycerin
Ilex Paraguariensis (Mate) Leaf Extract
Isopropyl Alcohol

Isopropyl Myristate
 Melissa Officinalis (Lemon Balm) Leaf Extract
 Silica
 Tocopheryl Acetate
 Triethanolamine
 Water

Signature care
Quality Guaranteed

Compare to Biofreeze® active ingredient*
NDC 00000-000-00

Cold Therapy Pain Relief Roller
4% MENTHOL Topical Analgesic

For the temporary relief of minor aches and pains of muscles and joints

2.5 FL OZ (73 mL)

Drug Facts

Active ingredient	Purpose
Menthol 4%	Topical Analgesic

Uses Temporary relief from minor aches and pains of sore muscles and joints associated with arthritis, backache, strains and sprains

Warnings
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Stop use and ask a doctor if • condition worsens, or if symptoms persist for more than 7 days, or clear up and reoccur.

Keep out of reach of children. If accidentally ingested get medical help or contact a Poison Control Center immediately.

Directions • Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
• Children under 2 years of age: Consult physician.

Inactive ingredients
Aloe Barbadensis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract, Camphor, Carbomer, FD&C Blue #1, FD&C Yellow #5, Glycerin, Ilex Paraguariensis (Mate) Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Triethanolamine, Water.

OUR PROMISE
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BETTER LIVING BRANDS LLC.
P.O. BOX 99,
PLEASANTON, CA 94566-0009
1-888-723-3929
www.betterlivingbrands.com

UPC PLACEMENT

*This product is not distributed by Performance Health, LLC., makers of the registered trademark Biofreeze®.

PAIN RELIEF ROLLER SIGNATURE CARE

menthol 4% gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-764
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	Menthol	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

ARCTIUM LAPPA ROOT (UNII: 597E9B3Z3)
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)
FRANKINCENSE (UNII: R9XLF1R1WM)
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)
Glycerin (UNII: PDC6A3C0OX)
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)
Isopropyl Alcohol (UNII: ND2M416302)
Isopropyl Myristate (UNII: 0RE8K4LNJS)
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
TROLAMINE (UNII: 9O3K93S3TK)
WATER (UNII: 059QF0KO0R)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-764-03	73 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	03/30/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/30/2018	

Labeler - Better Living (009137209)

Registrant - Product Quest Mfg (927768135)

Establishment			
Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(21130-764) , label(21130-764)