

PERFORM- menthol spray
Performance Health LLC

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.

Perform

Active Ingredients

Menthol USP 10.4%

Purpose

Cooling Pain Relief

Uses:

Soothing On-The-Go temporary relief from minor aches and pains associated with sore muscles, strains, joint discomfort, arthritis.

Warnings:

For external use only.

Flammable:

Keep away from excessive heat or open flame.

Ask a Doctor Before Using This Product If You: Have sensitive skin, are pregnant or are breastfeeding.

When Using This Product:

- Avoid contact with eyes or mucous membranes
- Do not apply to wounds, damaged or irritated skin, or if excessive irritation develops
- Do not bandage or use with a heating pad or device, ointments, creams, sprays, liniments

Stop Use and Ask a Doctor If:

Condition worsens, symptoms persist more than 7 days, or clear up and reoccur.

Keep Out of Reach of Children:

If ingested, get medical help. Contact Poison Control Center immediately.

Directions:

- **Adults / Children 12 years and older:** Apply on to affected area up to 4 times daily
- **Children under 12 years of age:** Consult a physician

Other Information:

Store in a cool, dry place out of direct sunlight.

Inactive Ingredients:

Arnica Extract, Eucalyptus Oil, Ilex Paraguariensis Extract, Lavender Oil, Lime Oil, Natural Camphor USP, Nutmeg Oil, Orange Oil, Peppermint Oil, Pine Oil, Polysorbate 20, SD Alcohol 39-C, Thyme Oil, Purified Water, White Tea Extract

Questions or Comments?

1-800-755-2584

Representative Labeling

PERFORM
COOL + SOOTHING
PAIN RELIEVING SPRAY
FOR SORE MUSCLES, JOINTS
BACK AND LOWER BODY

FAST-ACTING MENTHOL FORMULA

4 FL OZ / 118 ML

360°
SPRAY FROM ANY ANGLE

PARABEN-FREE

Drug Facts

Active Ingredients
Menthol USP 10.4%
Purpose
Cooling Pain Relief

Uses: Soothing temporary relief from minor aches and pains associated with sore muscles, strains, joint discomfort and arthritis.

Warnings:
For external use only.

Flammable: Keep away from excessive heat and open flame. **Contents Under Pressure, Do Not Puncture Or Incinerate, Do Not Store At Temperature Above 120°F.**

Ask a Doctor Before Using If You: Have sensitive skin, are pregnant or are breastfeeding.

When Using This Product:
• Avoid contact with eyes or mucous membranes • Do not apply to wounds, damaged or irritated skin, or if excessive irritation develops • Do not bandage or use with a heating pad or device, ointments, creams, sprays, liniments • Wash hands with cool water after using

Stop Use and Ask Doctor If: Condition worsens, symptoms persist more than 7 days, or clear up and reoccur.

Keep Out of Reach of Children: If ingested, get medical help. Contact Poison Control Center immediately.

Directions:
• **Adults/Children 12 years and older:** Spray on to affected area up to 4 times daily.
• **Children under 12 years of age:** Consult a physician.

Other Information: Store in a cool, dry place with lid closed tightly.

Inactive Ingredients: Alcohol Denat., Arnica Montana Flower Extract, Camellia Siniensis Leaf Extract, Camphor, Citrus Aurantiifolia (Lime) Oil, Citrus Aurantium Dulcis (Orange) Peel Oil, Eucalyptus Globulus Leaf Oil, Ilex Paraguariensis Leaf Extract, Lavandula Angustifolia (Lavender) Oil, Mentha Piperita (Peppermint) Oil, Myristica Fragrans (Nutmeg) Kernel Oil, Pinus Palustris Oil, Polysorbate-20, Thymus Vulgaris (Thyme) Flower/Leaf Oil, Water.

Questions or Comments? info@performpainrelief.com
1-800-755-2584

No Animal Testing Made in U.S.A.

NO NSAIDS, IBUPROFEN, ASPIRIN OR SALICYLATE

DOT SP 15792 . M5706
DISTRIBUTED BY:
Performance Health, LLC
Akron, OH 44310
12128 REV 6

7 31124 44410 3
NDC 59316 - 109 - 29

PERFORM

menthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-109
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	104 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA (UNII: O80TY208ZW)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
LIME OIL (UNII: UZH29XGA8G)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
NUTMEG OIL (UNII: Z1CLM48948)	
ORANGE OIL (UNII: AKN3KSD11B)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WHITE PINE OIL (UNII: HA5CX6676U)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
THYME OIL (UNII: 2UK410MY6B)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-109-27	10 in 1 BOX	01/10/2013	
1		1 mL in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:59316-109-29	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	01/10/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/10/2013	

Labeler - Performance Health LLC (794324061)**Establishment**

Name	Address	ID/FEI	Business Operations
Tapemark Company		006154595	manufacture(59316-109)

Establishment

Name	Address	ID/FEI	Business Operations
Span Packaging Services LLC		557434805	manufacture(59316-109)