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

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	12/31/2018
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		

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)