

PERFORM COOL AND SOOTHING PAIN RELIEVING- menthol gel
RB Health (US) 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® COOL and SOOTHING PAIN RELIEVING

Drug Facts

Active ingredient

Menthol 3.5%

Purpose

Pain Relieving Gel

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only.

Flammable:

Keep away from excessive heat or open flame

When using this product

- use only as directed
- avoid contact with the eyes or on mucous membranes
- do not apply to wounds or damaged skin
- do not apply to irritated skin or if excessive irritation develops
- do not bandage tightly or use with heating pad or device

Stop use and ask a doctor if

- you experience pain, swelling or blistering of the skin
- condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days

- arthritic pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age

If pregnant or breast-feeding, ask a health professional before use.

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

Directions

- adults and children 2 years of age and older: rub a thin film over affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a physician
- wash hands after use with cool water

Other information

- store at 20-25°C (68-77°F)
- store in a cool dry place away from direct sunlight

Inactive ingredients

Aloe Barbadensis Leaf Extract, Arnica Montana Flower Extract, Blue 1, Camellia Sinensis Leaf Extract, Carbomer, Citrus Aurantifolia (Lime) Oil, Citrus Aurantium Dulcis (Orange) Peel Oil, Eucalyptus Globulus Leaf Oil, Glycerin, Hypericum Perforatum Oil, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Lavandula Hybrida Oil, Mentha Piperita (Peppermint) Oil, Myristica Fragrans (Nutmeg) Kernel Oil, Pinus Sylvestris Leaf Oil, Polysorbate 20, Silica, Thymus Vulgaris (Thyme) Flower/Leaf Oil, Triethanolamine, Water

Questions or comments?

1-800-246-3733

Dist. by: RB Health (US), Parsippany, NJ 07054-0224

PRINCIPAL DISPLAY PANEL - 118 mL Tube Label

NDC 59316-111-20

PERFORM[®]

MENTHOL-PAIN
RELIEVING
GEL

COOL + SOOTHING

FOR SORE MUSCLES
AND JOINTS

FAST-ACTING

4 FL OZ (118 mL)

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
LIME OIL, COLD PRESSED (UNII: UZH29XGA8G)	
ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPERICUM OIL (UNII: OZU2FC70HY)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LAVANDIN OIL (UNII: 9RES347CKG)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
NUTMEG OIL (UNII: Z1CLM48948)	
PINE NEEDLE OIL (PINUS SYLVESTRIS) (UNII: 5EXL5H740Y)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
THYME OIL (UNII: 2UK410MY6B)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KOOR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-111-20	1 in 1 CARTON	05/18/2015	
1		118 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:59316-111-10	3 mL in 1 TUBE; Type 0: Not a Combination Product	05/18/2015	12/31/2023
3	NDC:59316-111-11	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2015	12/31/2023

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/18/2015	

Labeler - RB Health (US) LLC (081049410)