# PERFORM COOL AND SOOTHING PAIN RELIEVING ROLL-ON- 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.

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#### PERFORM COOL AND SOOTHING PAIN RELIEVING ROLL-ON

## **Drug Facts**

## **Active Ingredients**

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 and open flame.

## When Using This Product:

- use only as directed
- Avoid contact with the eyes or 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 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 20-25C (68-77F)
- store in a cool dry place away from direct sunlight

## **Inactive Ingredients:**

Aloe Barbadensis Leaf Extract, Arnica Montana Flower Extract, Blue 1, Camelia Sinensis Leaf Extract, Carbomer, Citrus Aurantifolia (lime) Oil, Citrus Auratium 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) Kerneol Oil, Pinus Sylvestris Leaf Oil, Polysorbate 20, Silica, Thymus Vulgaris (Thyme) Flower/Leaf Oil, Triethanolamine, Water.

## **Questions or Comments?**

1-800-246-3733

#### PRINCIPAL DISPLAY PANEL - 89 mL Bottle Label

NDC 59316-112-10

PERFORM®

MENTHOL-PAIN
RELIEVING
GEL
COOL + SOOTHING
FOR SORE MUSCLES
AND JOINTS

**FAST-ACTING** 

**ROLL-ON** 

3 FL OZ (89 mL)



## PERFORM COOL AND SOOTHING PAIN RELIEVING ROLL-ON

menthol gel

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-112		
Route of Administration	TOPICAL				

# Active Ingredient/Active Moiety Ingredient Name MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A) Basis of Strength MENTHOL, UNSPECIFIED FORM in 1 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: 2R040NI662)		

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: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:59316-112- 10	1 in 1 CARTON	05/18/2015			
1		89 mL in 1 BOTTLE; 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	05/18/2015			

## Labeler - RB Health (US) LLC (081049410)

Revised: 2/2022 RB Health (US) LLC