# THERAPEUTIC RELIEF PREFERRED PLUS PHARMACY- menthol gel Kinray Inc.

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**

Menthol 2.0%

#### Uses

For the temporary relief of minor aches and pains of muscles and joints associated with: simple backache, arthritis, strains, bruises, and sprains.

#### **Warnings**

**For external use only. When using this product**: avoid contact with the eyes, do not bandage tightly, do not apply to wounds or damaged skin, and do not use with heating pads of other heating devices. **Stop use and ask doctor if**: condition gets worse, symptoms last more than 7 days, or symptoms clear up and occur again in a few days.

#### **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: do not use, consult a doctor.

#### **Inactive ingredients**

Ammonium Hydroxide, Carbomer, Cupric Sulfate, Blue 1, Isopropyl Alcohol, Magnesium Sulfate, Sodium Hydroxide, Thymol, Water.

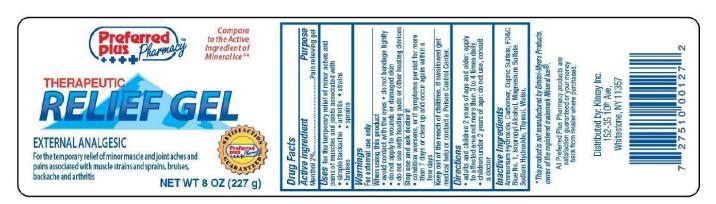
### **Purpose**

Pain relieving gel.

#### Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

## Therapeutic Relief Gel External Analgesic.



menthol gel

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61715-021

Route of Administration TOPICAL

### **Active Ingredient/Active Moiety**

ı	8 ** * * * * * * * * * * * * * * * * *		
l	Ingredient Name	Basis of Strength	Strength
ı	Menthol (UNII: L7T10 EIP3A) (Menthol - UNII:L7T10 EIP3A)	Me ntho l	2 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
Ammonia (UNII: 5138Q19F1X)				
Carbomer 934 (UNII: Z135WT9208)				
Cupric Sulfate (UNII: LRX7AJ16DT)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
Isopropyl Alcohol (UNII: ND2M416302)				
Magnesium Sulfate (UNII: DE08037SAB)				
Sodium Hydroxide (UNII: 55X04QC32I)				
Thymol (UNII: 3J50 XA376E)				
Water (UNII: 059QF0KO0R)				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:61715-021-08	227 g in 1 JAR					

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/15/2013	

# **Labeler** - Kinray Inc. (012574513)

Revised: 6/2013 Kinray Inc.