DAREDEVIL STRENGTH MUSCLE AND ARTHRITIS PAIN RELIEVING ROLL ON-
menthol gel
DDR Products, 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.

DAREDEVIL STRENGTH Muscle & Arthritis Pain Relieving Roll On

DRUG FACTS

Active Ingredient:

Menthol 10.00%

Topical Analgesic

Indications:

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

Warnings:

- For external use only.

- Avoid contact with eyes.

- If symptoms persist for more than seven days, discontinue use and consult physician.

Keep out of reach od children.

If swallowed, consult physician.

Do not apply

- to wounds or damaged skin.

- Do not bandage tightly.

- If pregnant or breast feeding,

contact physician prior to use.

Directions:

- Adults and children two-years of age or older: Apply to affected area not more than three to four times daily.

- Children under two years of age: consult a physician.

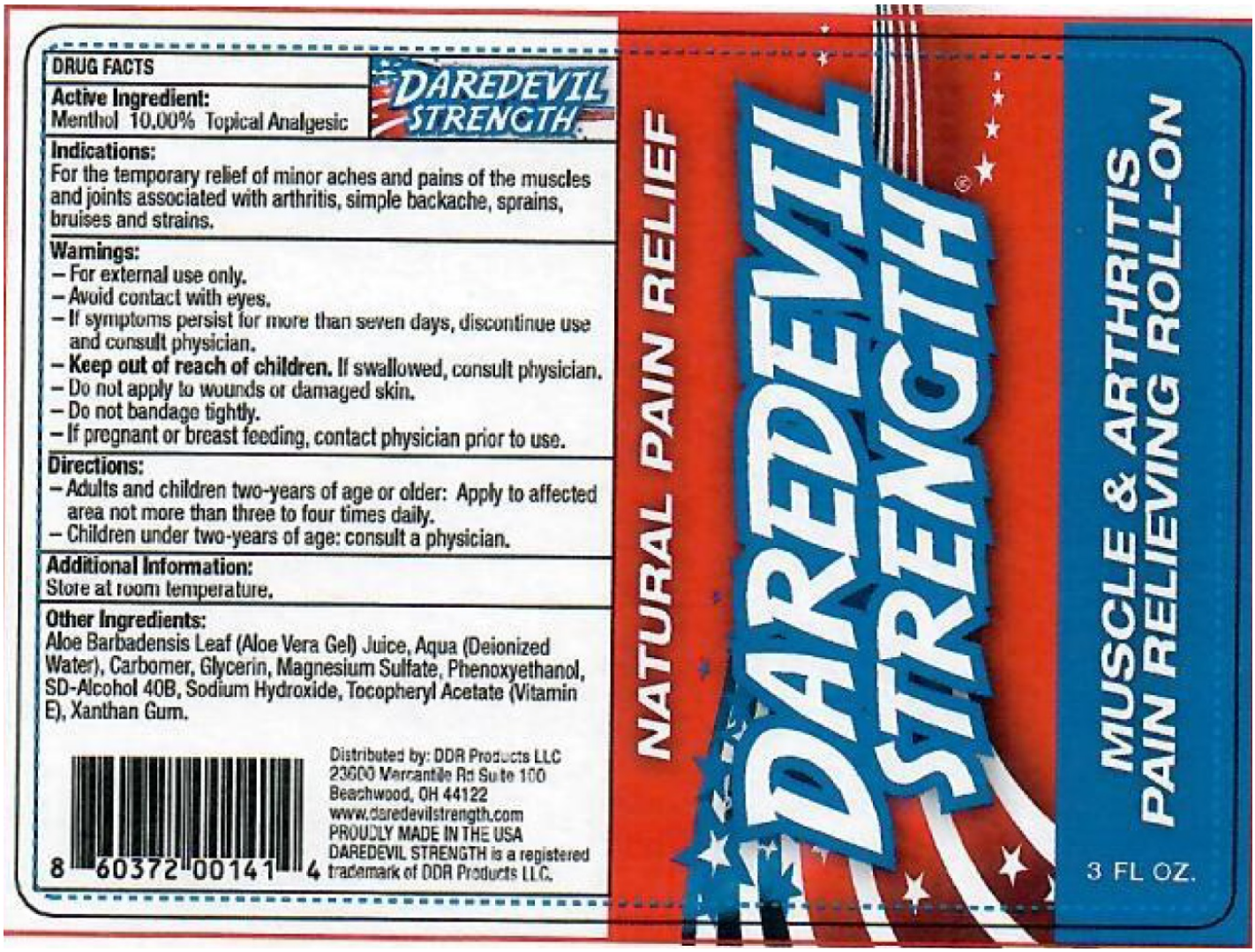
Additional Information:

Store at room temperature.

Other Ingredients:

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Carbomer, Glycerin, Magnesium Sulfate, Phenoxyethanol, SD-Alcohol 40B, Sodium Hydroxide, Tocopheryl Acetate (Vitamin E), Xanthan Gum.

Package Labeling:



DAREDEVIL STRENGTH MUSCLE AND ARTHRITIS PAIN RELIEVING ROLL ON

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71977-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71977-010-03	88.72 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/25/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/25/2018	

Labeler - DDR Products, LLC (080781689)

Revised: 11/2018 DDR Products, LLC