

4RLF TOPICAL ANALGESIC- menthol cream
Rinati Skin, 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.

RINATI - JEUNESSE - 4RLF Topical Analgesic (76849-201)

ACTIVE INGREDIENTS

Menthol 0.10%

PURPOSE

TOPICAL ANALGESIC

USES

For the temporary relief of pain from minor burns, sunburn, minor cuts, scrapes, and insect bites.

WARNINGS

For external use only. When using this product ■ Avoid contact with eyes. In case of eye contact, flush eyes with water. ■ If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician.

■ Keep out of reach of children.

If swallowed, get medical help.

DIRECTIONS FOR USE

■ Adults and children 2 years of age or older:

Apply to the desired area and gently rub into the skin, not more than 3 to 4 times daily. ■ Children under the age of 2: Consult a physician.

INACTIVE INGREDIENTS

Propylene Glycol, Ocimum Tenuiflorum Callus Culture Lysate, Glycerin, Dimethyl Sulfone, Water, Withania Somnifera Root Extract, Piper Nigrum (Pepper) Fruit Extract, Gluconolactone, Sodium Benzoate, Citric Acid, Xanthan Gum, Citrus Aurantium Dulcis (Orange) Oil, Hydroxyethylcellulose.

PIPER NIGRUM WHOLE (UNII: 49L10LI8DN)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CITRUS AURANTIUM FRUIT OIL (UNII: 59JDQ5VT0T)	
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76849-201-11	1 in 1 CARTON	08/23/2021	
1		10 in 1 BLISTER PACK		
1		1 mL in 1 VIAL; 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	08/23/2021	

Labeler - Rinati Skin, LLC (109530208)

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Rinati Skin, LLC