

ANALGESIC- menthol spray

Ouwee Jones, 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.

Ouwee Jones PAIN RELIEF SPRAY

Pain Spray

Drug Facts

Active Ingredients

USP Menthol 7%

Purpose

Topical Analgesic

Uses

Temporary relief of jellyfish stings.

Warnings

For external use only

Flammable. Keep away from flame.

Keep out of reach of children. If swallowed get medical help or contact a poison center right away. Avoid contact with eyes. Do not apply to open wounds or damaged skin. Do not bandage tightly. Consult a doctor if excessive skin irritation occurs, or if you are prone to allergic reactions to salicylates, including aspirin. If condition worsens, if symptoms persist for more than 7 days or clear up and recur again within a few days, discontinue use of this product and consult a doctor.

Directions

For adults and children 2 years of age and older: Shake well and apply to affected area not more than 3-4 times daily. Will not stain clothing. For children under 2 years of age, consult a doctor.

Other Information

Store at room temperature.

Inactive Ingredients

Water, Isopropyl Alcohol, Glycerol, Eucalyptus Leaf Oil, Wintergreen Leaf Oil, Peppermint Oil, Coconut Oil.

Questions or Comments

**855-37-OUWEE or
www.ouweejones.com**

Distributed By:

OuWee Jones Co.
 PO Box 118, Mobile, AL 36601
 www.ouweejones.com

PRINCIPAL DISPLAY PANEL

NDC 76417-8200-1



Ou! Wee!

Jellyfish Sting Relief

#1 Recommended Jellyfish Pain Relief Spray

4 fl. oz. (118 ml)

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ANALGESIC			
menthol spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76417-8200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
menthol (UNII: L7T10EIP3A) (menthol - UNII:L7T10EIP3A)	menthol	700 mL in 1 L

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
isopropyl alcohol (UNII: ND2M416302)	
glycerin (UNII: PDC6A3C0OX)	
eucalyptus oil (UNII: 2R04ONI662)	
methyl salicylate (UNII: LAV5U5022Y)	
peppermint oil (UNII: AV092KU4JH)	
coconut oil (UNII: Q9L0O73W7L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76417-8200-1	0.118 L in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/26/2011	

Labeler - Ouwee Jones, LLC (969347462)**Registrant** - Safetec of America, Inc. (874965262)**Establishment**

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE

Revised: 10/2011

Ouwee Jones, LLC