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

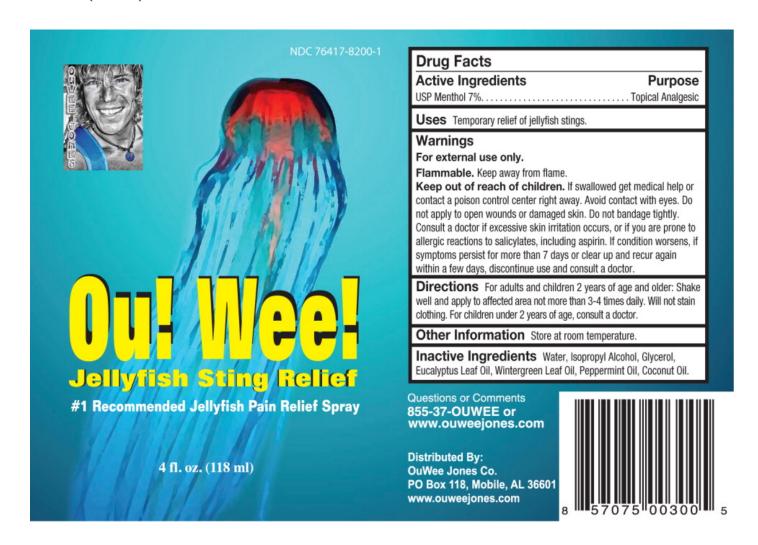
NDC 76417-8200-1

Ou! Wee!

Jellyfish Sting Relief

#1 Recommended Jellyfish Pain Relief Spray

4 fl. oz. (118 ml)



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: L7T10 EIP3A) (menthol - UNII:L7T10 EIP3A)	menthol	700 mL in 1 L		

Inactive Ingredients			
Ingredient Name	Strength		
water (UNII: 059QF0KO0R)			
isopropyl alcohol (UNII: ND2M416302)			
glycerin (UNII: PDC6 A3C0 OX)			
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