

C.D.M.A ICY COOL- cold therapy muscle spray
Sklar BOV Solutions 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.

C.D.M.A. Icy Cool

Active Ingredient Purpos

Menthol 10.5% Topical Analgesic

Uses - Topical Analgesic

INDICATIONS AND USAGE

Temporary relief form minor aches and pains of sore muscles and joints associated with arthritis backache, strains and sprains

Warning

FOR EXTERNAL USE ONLY. Flammaable. Keep away form excessive heat of open flame. CONTENTS UNDER

PRESSURE. DO NOT PUNCTURE OR INCINERATE. DO NOT STORE AT TEMPERATURE ABOVE 120°F.

When using this product; Avoid contact with eyes or mucous membranes. Do not apply to wounds or damages skin.

Do not use with others sprays, ointments, creams, sprays of liniments. Do not apply to irritated skin or if excessive

irritation develops. Do not bandage. Wash hands after use with cold water. Do not use with heating pad or device.

Stop Use and Ask a Doctor if: Condition worsens. If symptoms persist for more than 7 days, of if symptons clean up and reoccur.

Keep out of reach of Children. If swallowed, het medical help or contact a Poison Control Center right away.

If Pregnant of Breastfeeding; Consult a doctor before use.

Directions

Adults and Children 12 years of age and older. Spray on the affected areas not more than 4 times daily, massage not

necceary. Children under 12 years of age, Consult Physicial

Inactive Ingredients:

Inactive Ingredients: Alcohol Denat., Arnica Montana Flower Extract. Calendula Officinalis Flower Extract, Camellia

Sinensis Leaf Extract, Chamomilla Recultita (Matricana) Flower Extract, Dimethyl Sulfone (MSM), Echinacea Augustifola

Extract, Ilex Paraguariensis Leaf Extract, Isopropyl Myristate, Juniperus Communis Fruit Extract, Water

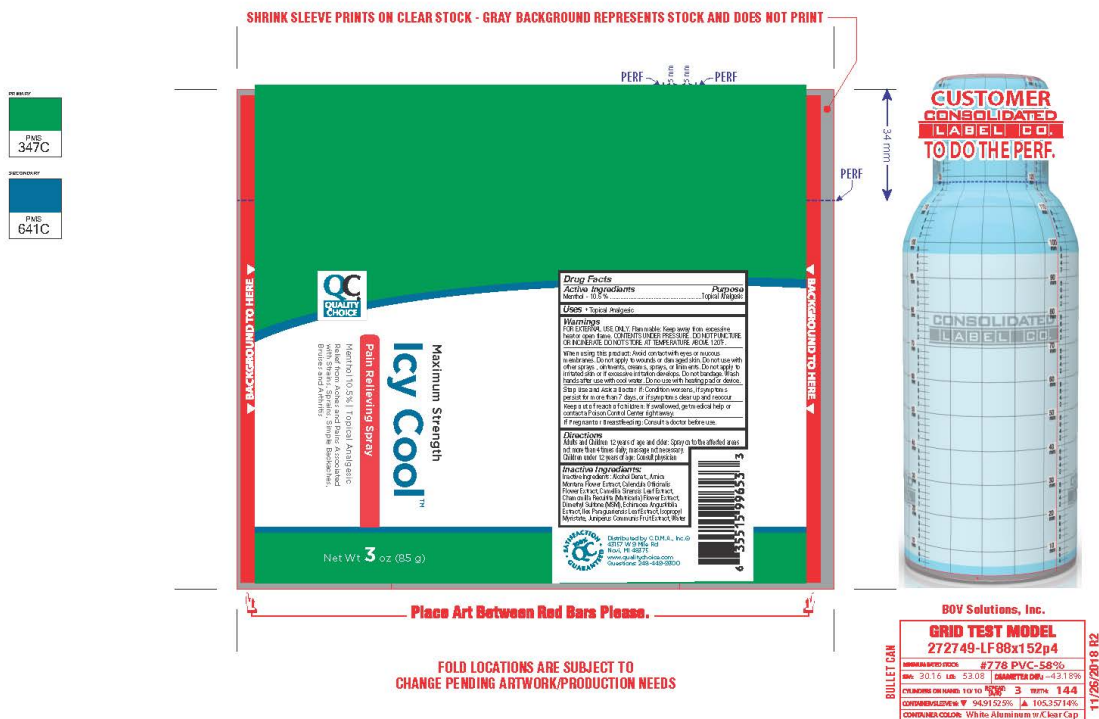
Distributed by C.D.M.A. Inc.©

43157 W 9 Mile Rd

Novi, MI 48375

www.qualitychoice.com

Questions: 248-449-9300



85 grams NDC52313-1131-1

Maximum Strength

Icy Cool™

Pain Relieving Spray

Menthol 10.5 % | Topical Analgesic

Relief from Aches and Pains Associated with Strains, Sprains, Simple Backaches, Bruises and Arthritis

Quality Choice®

C.D.M.A ICY COOL

cold therapy muscle spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52313-1131
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	105 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA (UNII: O80TY208ZW)	
CAMELLIA SINENSIS WHOLE (UNII: C5M4585ZBZ)	
JUNIPERUS COMMUNIS WHOLE (UNII: 464910T5N9)	
CHAMOMILE (UNII: FGL3685T2X)	
ALCOHOL (UNII: 3K9958V90M)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)	
WATER (UNII: 059QF0KO0R)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52313-1131-1	85 g in 1 CAN; Type 0: Not a Combination Product	06/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/23/2020	

Labeler - Sklar BOV Solutions Inc (800463486)

Registrant - Sklar BOV Solutions, Inc (800463486)

Establishment

Name	Address	ID/FEI	Business Operations
Sklar BOV Solutions, Inc		800463486	manufacture(52313-1131)

Revised: 1/2022

Sklar BOV Solutions Inc