ROCKSAUCE ICY COLD PAIN RELIEF- menthol gel
Implus Footcare, 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.

RockSauce®
ICY COLD PAIN RELIEF GEL

ACTIVE INGREDIENT

Menthol6%

PURPOSE

Topical Analgesic

USES:

Provides soothing cold to sore muscles and joints.

WARNINGS:

For external use only. Avoid contact with eyes, mucous membrane or broken skin.

When using this product, do not:

heat, microwave, add to hot water or any container where heating water may cause splattering and result in burns, use in eyes or directly on mucus membrane, take by mouth or place in nostrils, apply to wounds or damaged skin.

Do not use otherwise than as directed.

Consult a doctor and discontinue use if irritation occurs.

Ask a health professional before use if pregnant or breastfeeding.

Ask a doctor before using if you have sensitive skin.

Keep out of reach of children:

In case of accidental ingestion, get medical help or call Poison Control Center right away. Not for children 5 years or younger.

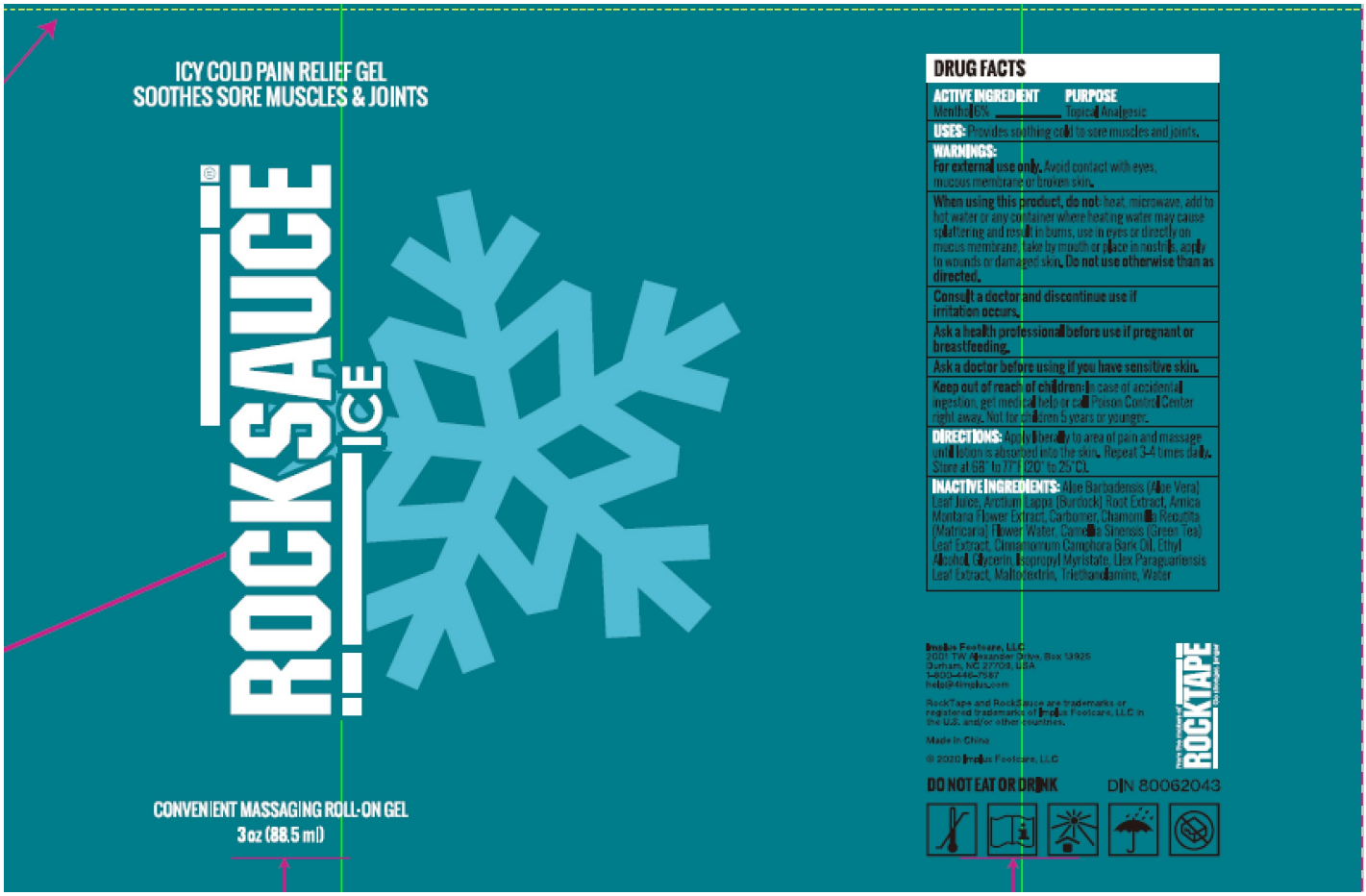
DIRECTIONS:

Apply liberally to area of pain and massage until lotion is absorbed into the skin. Repeat

3-4 times daily. Store at 68° to 77 °F(20° to 25°C).

INACTIVE INGREDIENTS:

Aloe Barbadensis(Aloe Vera) Leaf Juice, Arctium Lappa(Burdock)Root Extract, Arnica Montana Flower Extract, Carbomer, Chamomilla Recutita (Matricaria) Flower Water, Camellia Sinensis(Green Tea) Leaf Extract, Cinnamomum Camphora Bark Oil, Ethyl Alcohol, Glycerin, Isopropyl Myristate, Ilex Paraguariensis Leaf Extract, Maltodextrin, Triethanolamine, Water



ROCKSAUCE ICY COLD PAIN RELIEF

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81683-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	8.3 g in 88.5 mL

Inactive Ingredients

Ingredient Name	Strength
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAMPHOR OIL (UNII: 75IZZ8Y727)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ALCOHOL (UNII: 3K9958V90M)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81683-003-01	88.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/18/2021	

Labeler - Implus Footcare, LLC (361531585)

Revised: 3/2021

Implus Footcare, LLC