ICE BLUE PAIN ALLEVIATING RUB- menthol, unspecified form, methyl salicylate, camphor (natural) gel
ICE BLUE PAIN ALLEVIATING RUB- menthol, unspecified form, methyl salicylate, camphor (natural) spray
Lemisol Corporation

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.

Drug Facts

Active Ingredients

Methyl Salicylate8%

Menthol 5.0%

Camphor 3.0%

Purpose

Topical analgesic

Topical analgesic

Topical analgesic

Uses provides temporary relief of minor aches and pains in muscles and joints associated with

- arthritis
- simple backache
- muscle strains
- sprains
- bruises
- cramps

Warnings:

For external use only

When using this product use only as directed

- do not bandage or apply heating pads
- do not apply to wounds or damaged skin
- avoid contact with eyes and mucous membranes

Stop use and ask a doctor if

- condition worsens
- irritation develops
- symptoms persist for more than 8 days or clear up and return

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed get medical help or contact a Poison Control immediately.

Directions

Adults and children over 12 years:

Apply generously to affected area

Massage until gel is completely absorbed by skin. Repeat as necessary

Children under 12 years: ask a doctor before use

Inactive Ingredients

DMDM Hydantoin, Eucalyptus Globulus Leaf Oil, FD&C Blue No 1, Glycerin, Isopropyl Alcohol, PEG-40 Hydrogenated Castor Oil, Purified Water.

Principal Display Panel – 8 oz Spray Label

Greaseless

SIN GRASA

Rx
Rysell®

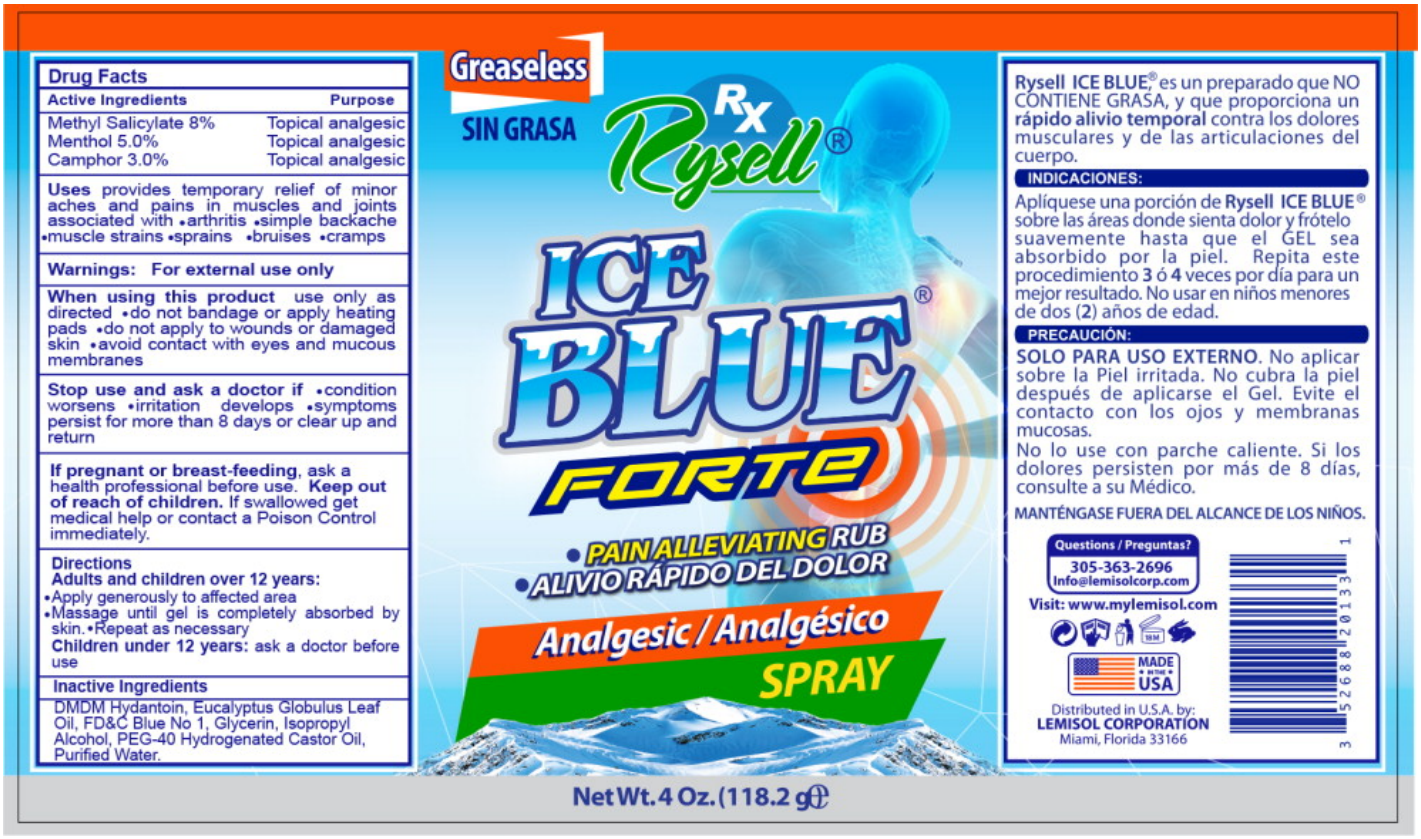
ICE
BLUE®
FORTE

- **PAIN ALLEVIATING RUB**
- **ALIVIO RÁPIDO DEL DOLOR**

Analgesic/ Analgésico

SPRAY

Net Wt. 4 Oz. (118.2 g)e



Principal Display Panel – 8 oz Gel Label

Greaseless

SIN GRASA

Rx
***Rysell*®**

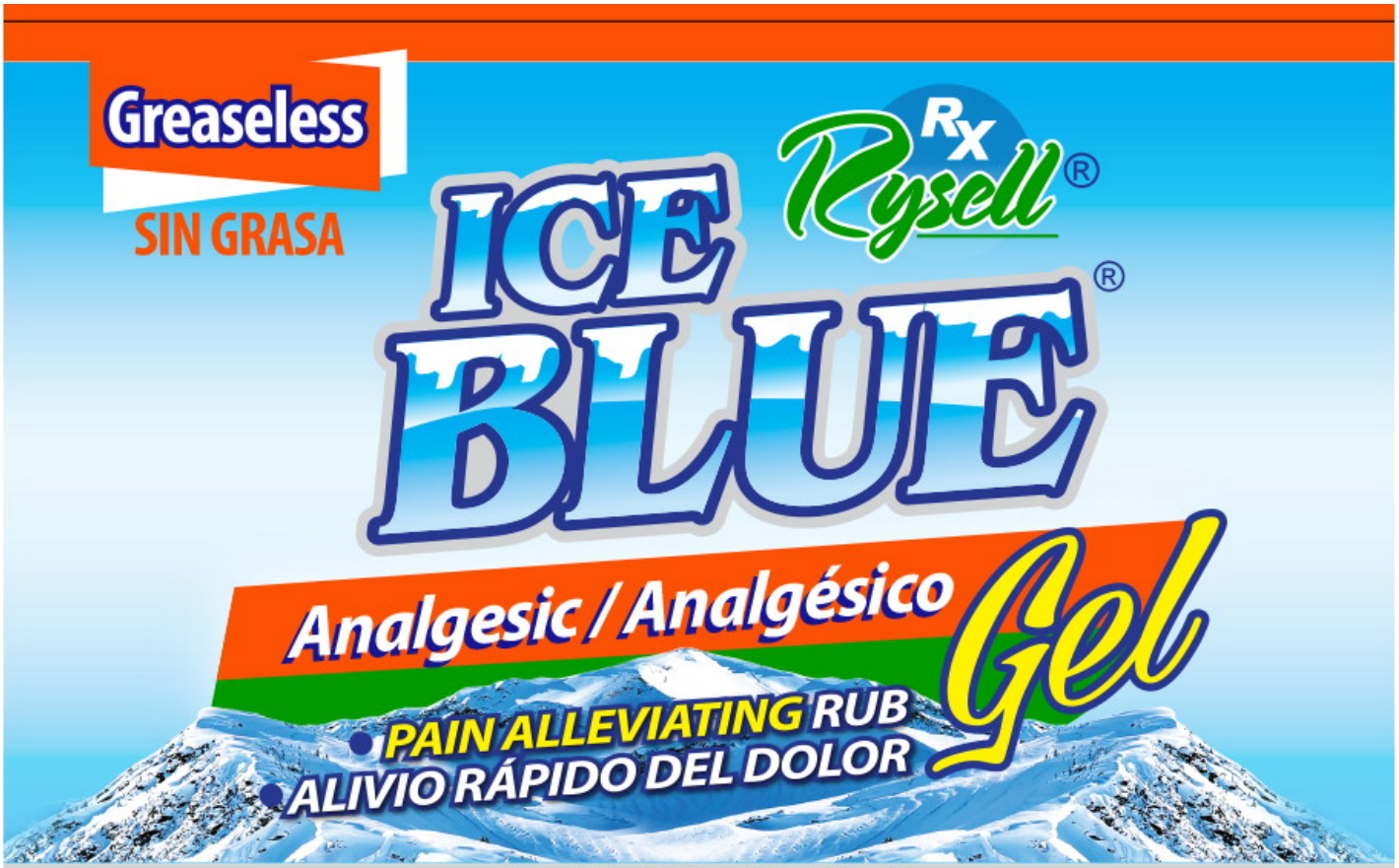
ICE
BLUE®

Analgesic/ Analgésico

Gel

- **PAIN ALLEVIATING RUB**
- **ALIVIO RÁPIDO DEL DOLOR**

Net Wt. 8 Oz. (226.7 g)e



Net Wt. 8 Oz. (226.7 g)

Drug Facts

Active Ingredients	Purpose
Menthol 2.5%	Topical analgesic
Methyl Salicylate2.2%	Topical analgesic
Camphor 0.3%	Topical analgesic

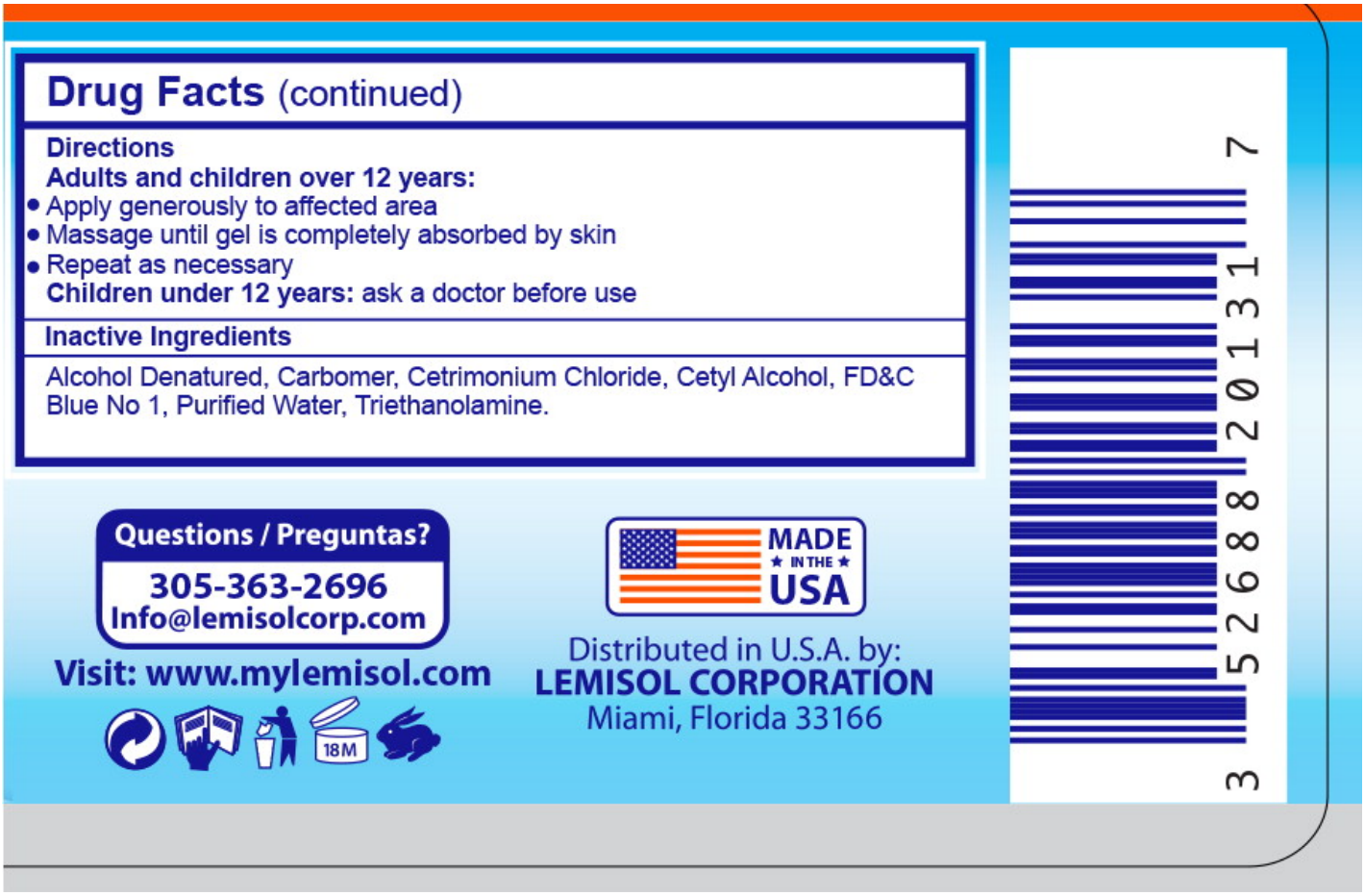
Uses provides temporary relief of minor aches and pains in muscles and joints associated with •arthritis •simple backache •muscle strains •sprains •bruises •cramps

Warnings: For external use only

When using this product •use only as directed •do not bandage or apply heating pads •do not apply to wounds or damaged skin •avoid contact with eyes and mucous membranes

Stop use and ask a doctor if •condition worsens •irritation develops. •symptoms persist for more than 8 days or clear up and return

If pregnant or breast-feeding, ask a health professional before use
Keep out of reach of children. If swallowed get medical help or contact a Poison Control immediately



ICE BLUE PAIN ALLEVIATING RUB

menthol, unspecified form, methyl salicylate, camphor (natural) gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82988-101
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	0.025 g in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.022 g in 1 g
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	0.003 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	

CETYL ALCOHOL (UNII: 936JST6JCN)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82988-101-08	226.7 g in 1 JAR; Type 0: Not a Combination Product	08/31/2022	
2	NDC:82988-101-16	453.5 g in 1 JAR; Type 0: Not a Combination Product	08/31/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/31/2022	

ICE BLUE PAIN ALLEVIATING RUB

menthol, unspecified form, methyl salicylate, camphor (natural) spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82988-102
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	0.05 g in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.08 g in 1 g
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	0.03 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DMDM HYDANTOIN (UNII: BYR0546TOW)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
Glycerin (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82988-102-04	118.2 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/31/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/31/2022	

Labeler - Lemisol Corporation (040708586)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetics & Cleaners International, LLC. DBA C&C Industries		018949897	MANUFACTURE(82988-101, 82988-102)

Revised: 8/2022 Lemisol Corporation