

MENTICOL FIRST AID ANTISEPTIC AND EXTERNAL ANALGESIC LOTION - menthol , alcohol lotion

Perfumeria Lemaitre S.A.

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.

Menticol first aid antiseptic and external analgesic lotion

Drug Facts

Active Ingredient	Purposes
Menthol 0.39 percent	External Analgesic
Ethyl Alcohol 70 percent	Antiseptic

Uses

For the temporary relief of pain associated with sunburn
For first aid use to decrease germs in minor cuts and scrapes

Warnings

For external use only.
Do not use in or near the eyes.
In case of deep or puncture wounds, consult your doctor.

Flammable, keep away from fire or flame

Avoid contact with the eyes.

If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

Keep out of reach of children.

If swallowed, get medical help or contact Poison Control Center right away.

Directions

Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
Apply to skin directly or with clean gauze, cotton or swab.
Children under 2 years of age: Consult a doctor.

Other information

Do not use if tamper evident seal is broken, missing or destroyed

FD C Blue #1, Fragrance, Water

Manufactured for

Perfumeria Lemaitre LLC

Katy, TX 77491

Product of Columbia

menticol

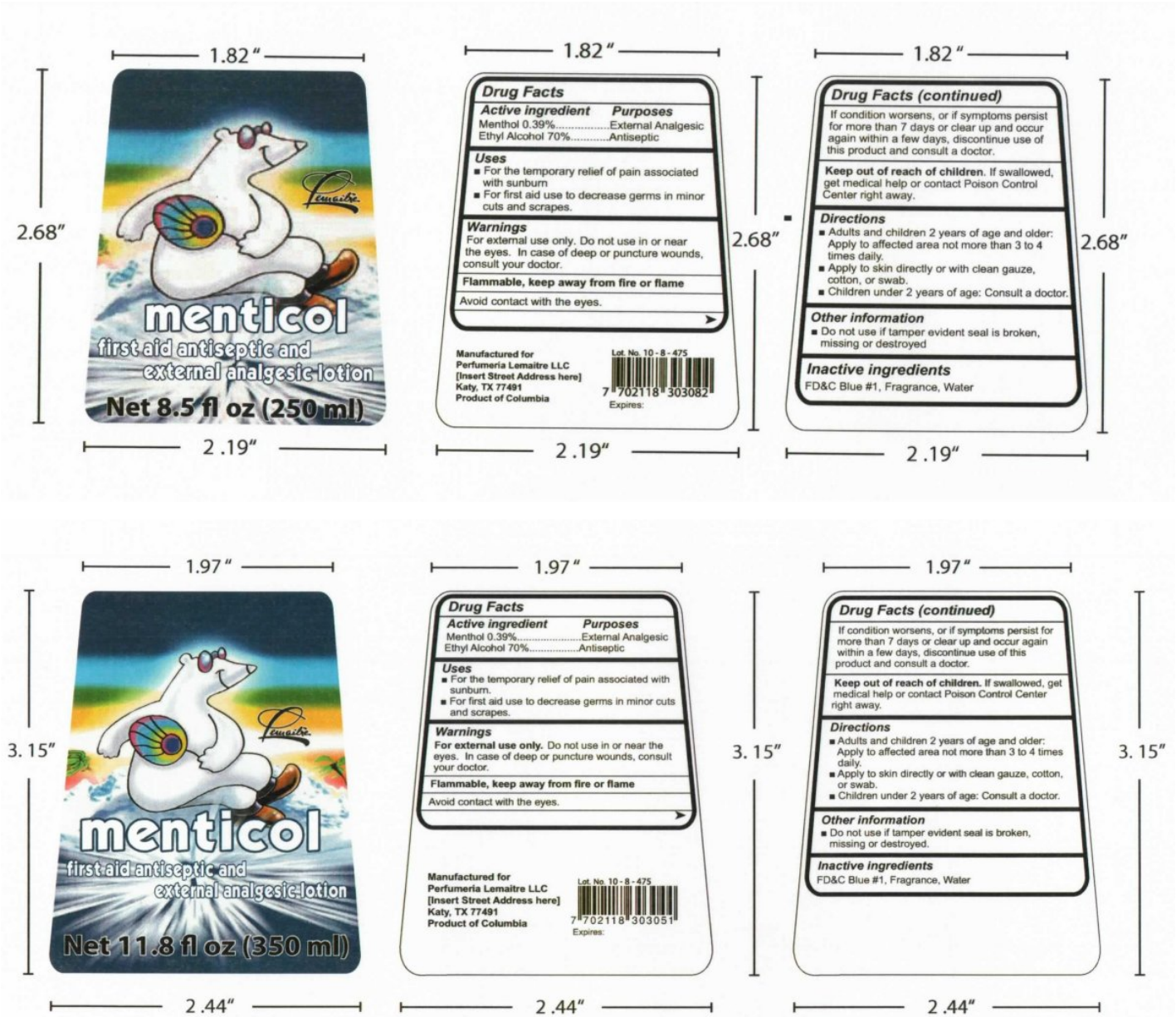
first aid antiseptic and external analgesic lotion

Net 8.5 fl oz 250 ml

menticol

first aid antiseptic and external analgesic lotion

Net 11.8 fl oz 350 ml



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MENTICOL FIRST AID ANTISEPTIC AND EXTERNAL ANALGESIC LOTION			
menthol , alcohol lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49 199 -100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	0.39 mL in 100 mL	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	70 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49 199-100-10	250 mL in 1 BOTTLE		
2	NDC:49 199-100-20	350 mL in 1 BOTTLE		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333	12/01/2009	

Labeler - Perfumeria Lemaitre S.A. (880262928)

Registrant - Perfumeria Lemaitre S.A. (880262928)

Establishment			
Name	Address	ID/FEI	Business Operations
Perfumeria Lemaitre S.A.		880262928	manufacture

Revised: 11/2009

Perfumeria Lemaitre S.A.