

SSENCARE- menthol liquid MIKYEONG KOREA CO.,LTD

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.

Menthol

Vanillyl Butyl Ether, Water, etc

Warming & Relaxing, Calming

1. Do not use in the following cases(Eczema and scalp wounds)

2.Side Effects

1)Due to the use of this druf if rash, irritation, itching and symptopms of hypersnesitivity occur dicontinue use and consult your phamacisr or doctor

3.General Precautions

1)If in contact with the eyes, wash out thoroughly with water If the symptoms are servere, seek medical advice immediately

2)This product is for exeternal use only. Do not use for internal use

4.Storage and handling precautions

1)If possible, avoid direct sunlight and store in cool and area of low humidity

2)In order to maintain the quality of the product and avoid misuse

3)Avoid placing the product near fire and store out in reach of children

Keep out of reach of children.

Exercise before / after, except for sensitive areas, massage the appropriate amount as necessary

for external use only



SSENCARE

menthol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72506-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
VANILLYL BUTYL ETHER (UNII: S2ULN37C9R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72506-0001-1	30 mL in 1 TUBE; Type 0: Not a Combination Product	04/06/2021	
2	NDC:72506-0001-2	80 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	04/06/2021	
3	NDC:72506-0001-3	100 mL in 1 TUBE; Type 0: Not a Combination Product	04/06/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/06/2021	

Labeler - MIKYEONG KOREA CO.,LTD (694790921)

Registrant - MIKYEONG KOREA CO.,LTD (694790921)

Establishment

Name	Address	ID/FEI	Business Operations
MIKYEONG KOREA CO.,LTD		694790921	label(72506-0001) , pack(72506-0001) , manufacture(72506-0001)