

AQUACOOL- menthol spray
Pharmanuco

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

MENTHOL

ALCOHOL, WATER, GLYCERIN, EUCALYPTUS GLOBULUS LEAF OIL, GLYCYRRHIZA (LICORICE) ROOT EXTRACT, BOSWELLIA SERRATA GUM EXTRACT, ALLANTOIN

To relieve pain

keep out of reach of the children

Spray proper amount to treatment area(s)

for external use only

1. Under normal room conditions, the shelf life is estimated at 2 years.
2. Recommended Use: Temporarily relieves minor aches and pains of muscles and joints associated with: simple backaches, arthritis, strains, bruises, sprains.
3. Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.
4. Rub in thoroughly until gel is absorbed.
5. Use with caution on sensitive areas.
6. It is recommended that you do a patch test before applying liberally to the skin.

AQUACOOOL

menthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70759-0004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C00X)				
ALLANTOIN (UNII: 344S277G0Z)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70759-0004-1	150 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/01/2016	08/09/2016
2	NDC:70759-0004-2	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/09/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	02/04/2016		

Labeler - Pharmanuco (687825097)

Registrant - Pharmanuco (687825097)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharmanuco		687825097	manufacture(70759-0004)