AQUACOOL RED 500- menthol gel
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

WATER, GLYCERIN, CABORBER, ACETYL GLUCOSAMINE, IPA, CAMPHOR, METHILPARABEN, KONIO NP-12, RHEODOL O120, EUCALYPTUS OIL, VANILLYL BUTYL ETER, SF1202, LEMON SCENTED TEA TREE OIL, RED102, SODIUM HYDROXIDE, HAMAMELIS VIRGINIANA (WITCH HAZEL) EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, LEPTOSPERMUM PETERSONII OIL, ARNICA MONTANA FLOWER EXTRACT

To relieve pain

keep out of reach of the children

Apply proper amount to desired area(s) and massage the applied area until it's absorbed to the skin thoroughly.

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.

AQUACOOL RED 500

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70759-0007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**

VANILLYL BUTYL ETHER (UNII: S2ULN37C9R)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70759-0007-1	120 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2016	05/02/2016
2	NDC:70759-0007-2	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/02/2016	

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(70759-0007)

Revised: 6/2016 Pharmanuco