# AQUACOOL BLUE 120- 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.

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#### **Drug Facts**

**MENTHOL** 

WATER, ISOPROPYL ALCOHOL, GLYCERIN, GLYCYRRHIZA URALENSIS, CARBOMER, CAMPHOR, NaOH, CI 42090, METHYLPARABEN, CASTOR OIL

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 BLUE 120**

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70759-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.2 g in 100 mL	

#### **Inactive Ingredients**

Ingredient Name	Strength
GLYCYRRHIZA URALENSIS (UNII: 42B5YD8F0K)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

P	Packaging			
#	# Item Code Package Description		Marketing Start Date	Marketing End Date
1	NDC:70759- 0001-1	120 mL in 1 TUBE; Type 0: Not a Combination Product	05/01/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/04/2016	
	part348	02/04/2016	

#### Labeler - Pharmanuco (687825097)

### Registrant - Pharmanuco (687825097)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pharmanuco		687825097	manufacture(70759-0001)	

Revised: 3/2021 Pharmanuco