

AQUACOOOL BLUE ROLL- 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, 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.

AQUACOOOL BLUE ROLL

menthol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70759-0003 |
| 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) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70759-0003-1 | 100 mL in 1 BOTTLE, WTH APPLICATOR; 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 | |

Labeler - Pharmanuco (687825097)

Registrant - Pharmanuco (687825097)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------|---------|-----------|-------------------------|
| Pharmanuco | | 687825097 | manufacture(70759-0003) |

Revised: 3/2021

Pharmanuco