ULTRA BLUE- 4% menthol gel
BNG Enterprises DBA Herbal Clean

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.

Active ingredient section

Menthol (4%)

Purpose

Topical Analgesic

Uses:

Temporarily relieves minor aches and pains of muscles and joints due to arthritis, simple backache, sprains, strains, bruises.

Warnings

For external use only.

Stop Use and Ask a Doctor If

• Condition worsens

• Symptoms last more than 7 days or clear up and occur again within a few days

• A rash or irritation develops

Keep out of reach of children

If pregnant or breastfeeding, ask a health professional before use. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

When Using This Product

• Do not apply to wounds or damaged skin

• Do not bandage tightly

• Do not use in or near the eyes; if product gets into eyes, rinse thoroughly with water

• Do not use with electric heating pad

Directions

• Adults and children 2 years and older, apply directly to affected area; not more than 3 or 4 times daily

• Children under 2 years, ask a doctor

Inactive Ingredients:

Purified Water, Propylene Glycol, Emu Oil, Methylsulfonylmethane (msm), Polyacrylamide (and) C13-

14 Isoparaffin and Laureth-7, C12-15 Alkyl Benzoate, Dimethicone, Dioctyl Adipate (and) Octyl Stearate (and) Octyl Palmitate, White Willow Extract, Propylene Glycol (and) Diazolidinyl Urea (and) Methylparaben (and) Propylparaben, Aloe Vera Gel, Panthenol, Ascorbic Acid, Capsicum Oleoresin, Cornflower Extract, Chamomile Extract, Feverfew Extract, Hypericum Extract, Calendula Extract, Linden Extract, Coriander Oil, Grape Seed Extract, Benzophenone-4, Polysorbate-20, Tetrasodium EDTA, Citric Acid, Fragrance, F D & C Blue #1 Lake

Ultra Blue tube front panel, back panel

ULTRA BLUE

4% menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70632-825
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	4.56 g in 114 g

Inactive Ingredients	
Ingredient Name	**Strength**
EMU OIL (UNII: 344821WD61)	

Product Characteristics			
Color	blue	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70632-825-04	5000 g in 1 TUBE; Type 0: Not a Combination Product	07/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/01/2018	

Labeler - BNG Enterprises DBA Herbal Clean (781993902)

Establishment

Name	Address	ID/FEI	Business Operations
Personal Care Performance Group		144297160	manufacture(70632-825)