EASE YOUR PAIN- menthol cream
Proximity Capital Partners LLC dba Asutra

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.

Menthol USP 4%

Menthol USP 4% ..... Topical Analgesic

For the temporary relief of minor aches and pains of muscles and joints associated with

- simple backache
- arthritis
- strains
- bruises
- sprains

Use only as directed.

For external use only. Keep away from excessive heat or flame.

When using this product:

- Avoid contact with eyes and mucous membranes
- Do not apply to wounds or damaged skin
- Do not bandage or use with a heating pad, other ointments, creams, sprays, or liniments

Stop use and ask doctor if:

- Condition worsens
- Symptoms persist for more than 7 days, or clear up and occur again within a few days

If pregnant or breastfeeding: Ask a health professional before using.

Keep out of reach of children. If accidentally ingested, get medical help or contact Poison Control Center immediately.

Adults and children 2 years of age and older:

- Apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age:

- Consult physician.

- Store in a cool, dry place.
- Avoid direct sunlight.
- Tamper-evident for your protection. Use only if safety seal is intact.
- Keep away from excessive heat or flame.

Purified Water, Ethyl Alcohol, Dimethyl Sulfone (MSM), Arnica Montana, Calendula Officinalis Flower Extract, Methyl Glucose Dioleate, Sodium Hydroxide, Baobab Oil, Carbomer, Citric Acid

888-819-6472

Monday - Friday, 9am - 5pm CT

Report any serious side effects to number above.

EASE YOUR PAIN

menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72683-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
ADANSONIA DIGITATA SEED OIL (UNII: 77MKL7AR5I)	
ARNICA MONTANA (UNII: O80TY208ZW)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ALCOHOL (UNII: 3K9958V90M)	
METHYL GLUCOSE DIOLEATE (UNII: FA9KFJ4Z6P)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72683-002-01	1 in 1 CARTON	01/21/2019	
1		85 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/21/2019	

Labeler - Proximity Capital Partners LLC dba Asutra (081214985)

Establishment

Name	Address	ID/FEI	Business Operations
BioLyte Laboratories, LLC		015560564	manufacture(72683-002)

Revised: 12/2020 Proximity Capital Partners LLC dba Asutra