LEADER ULTRA STRENGTH PAIN RELIEVING- menthol patch
Cardinal Health, Inc.

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 **Purpose**

Menthol 5%.....Topical Analgesic

Uses

temporarily relieves mino aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only.

Do not use

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if you have

- redness over the affected area

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- open pouch and remove patch
- if desired, cut patch to size
- peel off protective backing and apply sticky side to affected area
- adults and children 12 years of age and older:apply to affected area not more than 3 to 4 times daily
- children under 12 years of age:consult a doctor

Other information

- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

butylated hydroxytoluene, carboxymethylcellulose sodium, castor oil, edetate disodium, gelatin, glycerin, isopropyl myristate, kaolin, magnesium aluminum hydroxide, methylparaben, polyacrylic acid, polysorbate 80, polyvinyl alcohol, purified water, sodium polyacrylate, sorbitan monooleate, tartaric acid, titanium dioxide

DISTRIBUTED BY

CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com

1-800-200-6313

LEADER ULTRA STRENGTH PAIN RELIEVING

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0185
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	50 mg

Inactive Ingredients	
Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CASTOR OIL (UNII: D5340Y2I9G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
KAOLIN (UNII: 24H4NWX5CO)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0185-1	1 in 1 BOX	11/28/2016	
1		5 in 1 POUCH		
1		1 in 1 PATCH; 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	11/28/2016	

Labeler - Cardinal Health, Inc. (097537435)

Revised: 12/2017 Cardinal Health, Inc.