LEADER EXTRA STRENGTH MEDICATED PAIN RELIEF PATCH- menthol patch
Cardinal Health

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 minor pain associated with:
- arthritis
- simple backache
- bursitis
- tendonitis
- muscle strains
- muscle sprains
- bruises
- cramps

Warnings

For external use only

If pregnant or breast-feeding, ask a health professional before use.

When using this product
- use only as directed
- do not bandage tightly or use with a heating pad
- avoid contact with eyes and mucous membranes
- do not apply to wounds or damaged skin

Stop use and ask a doctor if:
- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present
- skin irritation develops

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions
- adults and children 12 years old
- peel off protective backing and apply sticky side to affected area
- should be used up to 8 hours
- should be used no more than 3 times a day
- children under 12 years of age consult a doctor

Other information
- store at room temperature, not to exceed 85°F (30°C)

Inactive ingredients

1,3-butylene glycol, aloe vera (powder), dibutylhydroxytoluene, disdoium edate, d-sorbitol solution,

gelatin, glycerine, kaolin, light liquid paraffin, magnesium aluminum hydrate, metacrylic acid butylacrylate copolymer, methyl parahydroxybenzoate, polysorbate 80, purified water, sodium metaphosphate, sodium polyacrylate, sorbitan monooleate, tartaric acid, titanium oxide, tocopherol acetate

DISTRIBUTED BY:

CARDINAL HEALTH

DUBLIN, OHIO 43017 USA

LEADER EXTRA STRENGTH MEDICATED PAIN RELIEF PATCH

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49781-083
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	50 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
1,3-BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALOE VERA FLOWER (UNII: 575DY8C1ER)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	

PARAFFIN (UNII: I9O0E3H2ZE)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TARTARIC ACID (UNII: W4888I119H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-083-70	1 in 1 BOX		
1		1 g in 1 PATCH		
2	NDC:49781-083-71	5 in 1 BOX		
2		1 g in 1 PATCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/25/2014	

Labeler - Cardinal Health (097537435)

Revised: 12/2014 Cardinal Health