SMART SENSE COLD AND HOT EXTRA STRENGTH MEDICATED - menthol patch Kmart Corporation

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 Listing

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. (1-800-222-1222)

Directions

- adults and children 12 years of age and older
- peel off protective backing and apply sticky side to affected area
- carefully remove backing from patch
- 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 86°F (30°C)

Inactive ingredients aloe vera, aluminum hydroxide, BHT, caster oil, disodium edetate, gelatin, glycerin, isopropyl myristate, kaolin, magnesium aluminometasilicate, methylparaben, polyethylene glycol monostearate, polysorbate 80, polyvinyl alcohol, polyvinyl pyrrlidone, purified water, sodium

polyacrylate, tartaric acid, titanium dioxide, tocopherol acetate. Release Liner: polypropylene, nonwoven material: polyester non-woven fabric.

Distributed By: Kmart Corporation

Hoffman Estates, IL 60179

Made in South Korea



SMART SENSE COLD AND HOT EXTRA STRENGTH MEDICATED

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49738-296
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	750 mg	

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	

BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A218 C7H19 T)	
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)	
WATER (UNII: 059QF0KO0R)	
TARTARIC ACID (UNII: W48881119H)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49738-296-25	1 in 1 CARTON		
1		5 in 1 POUCH		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/30/2013	

Labeler - Kmart Corporation (008965873)

Revised: 6/2013 Kmart Corporation