ASSURED EXTRA STRENGTH COLD N HOT - menthol patch
Greenbrier International, 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.

Drug Facts

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 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 of age and older: apply to affected area not more than 3 to 4 times daily
- Children under 12 years of age: do not use, consult a doctor
- For easy application: partially peel back protective film and apply exposed patch to site of pain. Carefully remove remaining film while pressing patch to skin for secure adhesion.

Inactive ingredients aloe vera, aluminum hydroxide, disodium EDTA, gelatin, kaolin, methacrylic acid copolymer, methylparaben, polysorbate 80, sorbitan monooleate, sorbitol solution, tartaric acid, titanium dioxide, tocopheryl acetate (vitamin E), water

Distributed by:

Greenbrier International, Inc.

500 Volvo Parkway

Chesapeake, VA 23320

Made in Korea

ASSURED EXTRA STRENGTH COLD N HOT

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:33992-8463
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	750 mg

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GELATIN (UNII: 2G86QN327L)	
KAOLIN (UNII: 24H4NWX5CO)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
SORBITOL (UNII: 506T60A25R)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-8463-2	1 in 1 CARTON		
1		2 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 - Greenbrier International, Inc. (610322518)

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