

DG HEALTH EXTRA STRENGTH MEDICATED- menthol patch

Dolgenercorp 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 minor pain associated with:

- arthritis
- simple backache
- bursitis
- tendonitis
- muscle strains
- muscle sprains
- bruises
- cramps

Warnings

For external use only

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, broken or irritated skin

Stop use and ask a doctor if:

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days

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

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

Directions adults and children over 12 years :

- remove backing from patch by grasping both ends firmly and gently pulling until backing separates in middle
- carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
- once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area
- apply one patch to affected area
- wear one patch up to 8 hours
- repeat as necessary, but no more than 3 times daily

Children 12 years or younger: ask a doctor

Other information

- store at room temperature

Inactive ingredients

aloe barbadensis leaf juice, aluminum hydroxide, BHT, castor oil, disodium edetate, gelatin, glycerin, isopropyl myristate, kaolin, magnesium

aluminate metasilicate, methylparaben, peg-40 stearate, polysorbate 80, polyvinyl alcohol, purified water, PVP, sodium polyacrylate, tartaric

acid, titanium dioxide, tocopherol acetate

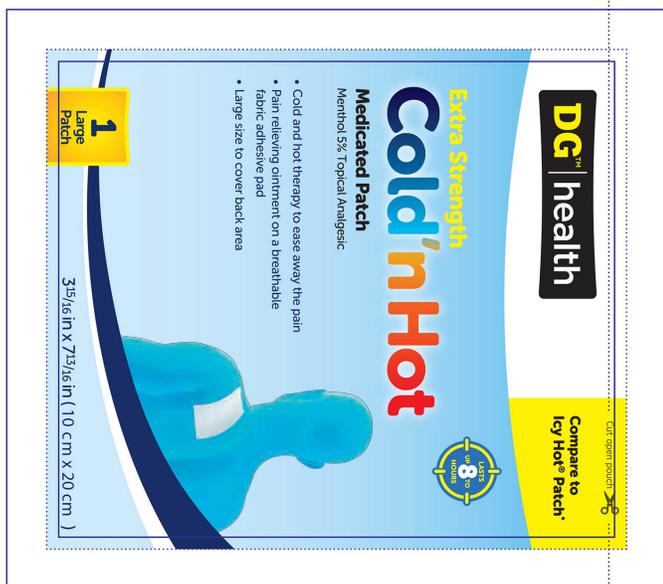
Distributed By:

Dolgenercorp. LLC

100 Mission Ridge

Goodlettsville, TN 37072

Made in Korea



DG HEALTH EXTRA STRENGTH MEDICATED

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:559 10-395
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)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CASTOR OIL (UNII: D5340Y2I9G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
KAOLIN (UNII: 24H4NWX5CO)	
SILODRATE (UNII: 9T3UU8T0QK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
WATER (UNII: 059QF0K00R)	
POVIDONES (UNII: FZ989GH94E)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TARTARIC ACID (UNII: W48881119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-395-01	1 in 1 CARTON	06/30/2013	
1		1 in 1 POUCH; 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	06/30/2013	

Labeler - Dolgencorp Inc (068331990)