

DG HEALTH PAIN RELIEVING- menthol patch
DOLGENCORP 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 Ingredients

Purpose

□Menthol 5.0%.....Topical Analgesic

□Uses

For temporary relief of minor aches and pains of muscles and joints 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

- 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 healthcare professional before use.

□Keep out of reach of children

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

□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 time 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, edetate, gelatin, glycerin, isopropyl myristate, kaolin, magnesium aluminum metasilicate, methylparaben, peg-40 stearate, polysorbate 80, polyvinyl alcohol, purified water, PVP, sodium polyacrylate, tartaric acid, titanium dioxide, tocopherol acetate

DISTRIBUTED BY

DOLGENCORP, LLC

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

MADE IN KOREA



DG HEALTH PAIN RELIEVING
menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-911
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: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-911-06	6 in 1 POUCH	09/03/2013	
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	09/03/2013	

Labeler - DOLGENCORP INC (06833190)

