

QC COLD AND HOT PAIN RELIEF - menthol patch

Quality Home Products

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

Menthol 5.0%

Purpose

Topical Analgesic Patch

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only

When using this product

- avoid contact with eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 10 years of age and older: Apply to affected area not more than 3 to 4 times daily
- Children under 10 years of age: do not use, consult a doctor

Inactive ingredients

Purified Water, Acrylic Acid, Aluminum Hydroxide, Carmellose sodium, 2-Ethylhexyl Acrylate, Glycerin, Isopropyl Myristate, Methyl Acrylate, Nonoxymol-30, Sodium Polyacrylate, Polyacrylic Acid, Polysorbate 80, Sorbitan Sesquioleate, Starch, Talc, Tartaric acid, Titanium Dioxide

package label

QC Cold and Hot Patch



QC COLD AND HOT PAIN RELIEF

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64525-5131
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	400 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ACRYLIC ACID (UNII: J94PBK7X8S)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL ACRYLATE (UNII: WC487PR91H)	
NONOXYNOL-30 (UNII: JJX07DG188)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W4888119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64525-5131-5	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	09/12/2011	

Labeler - Quality Home Products (205554157)

Revised: 9/2011

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