

FAMILY CARE BACK PAIN THERAPY - camphor (synthetic), menthol, and capsicum oleoresin patch

UNITED EXCHANGE CORP

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 Ingredients	Purpose
Camphor 80mg / patch	Topical Analgesic
Menthol 24mg / patch	Topical Analgesic
Capsicum Extract 16mg / patch	Topical Analgesic

Uses

For temporary relief of pains.

Warnings

FOR EXTERNAL USE ONLY

When using this product

- Use only as directed
- Do not get into eyes or on mucous membranes
- Do not apply to wounds, damaged or irritated skin
- Do not bandage or cover with any type of wrap except clothing
- Do not use with a heating pad or apply external heat
- Do not use 1 hour prior to bathing or 30 minutes after bathing

Stop use and ask a doctor if

- Condition worsens
- Severe skin irritation occurs
- Pain persists for more than 7 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 Poison Control Center right away.

Directions

- Adults and children 12 years and over apply to affected area; change patch 1 to 2 times daily
- Children under 12 years, consult doctor before use
- How to apply:
 - Clean and dry affected area
 - Cut open pouch and remove patch
 - Remove protective film and apply directly to area of pain
 - Apply to affected area not more than 3 times daily
 - Wash hands with soap after applying patch
- Reseal pouch containing unused patches

Other Information

This product may cause allergic reaction in some individuals. Store in cool dry place away from direct sunlight.

Inactive Ingredients

Aluminium glycinat, eucalyptus oil, glycerin, kaolin, mentha oil, polysorbate 80, propylene glycol, sodium carboxymethylcellulose, sodium polyacrylate, polyacrylic acid solution, sorbitol solution, hydrotalcite, water

Distributed By:

UNITED EXCHANGE CORP.

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CERRITOS, CA 90703

MADE IN KOREA



FAMILY CARE BACK PAIN THERAPY

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Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:65923-901

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	80 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	24 mg
CAPSICUM OLEORESIN (UNII: UW86K581WY) (CAPSICUM OLEORESIN - UNII:UW86K581WY)	CAPSICUM OLEORESIN	16 mg

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
KAOLIN (UNII: 24H4NWX5CO)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-901-37	1 in 1 BOX		
1		2 in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/27/2011	

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