MEDICATED PAIN RELIEF - menthol patch
American Sales Company

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%

Purpose
Topical analgesic

Use
- temporarily relieves minor aches and pains of muscles and joints associated with:
- ◦ simple backache
- ◦ arthritis
- ◦ bruises
- ◦ sprains
-

Warnings

For external use only

Do not use
- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before using if you have
- redness over the affected area

When using this product
- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if
- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

Keep out of reach of children.

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

Directions
- open pouch and remove patch
- if desired, cut patch to size

- peel off protective backing and apply sticky side to affected area
- 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: consult a doctor

Other information

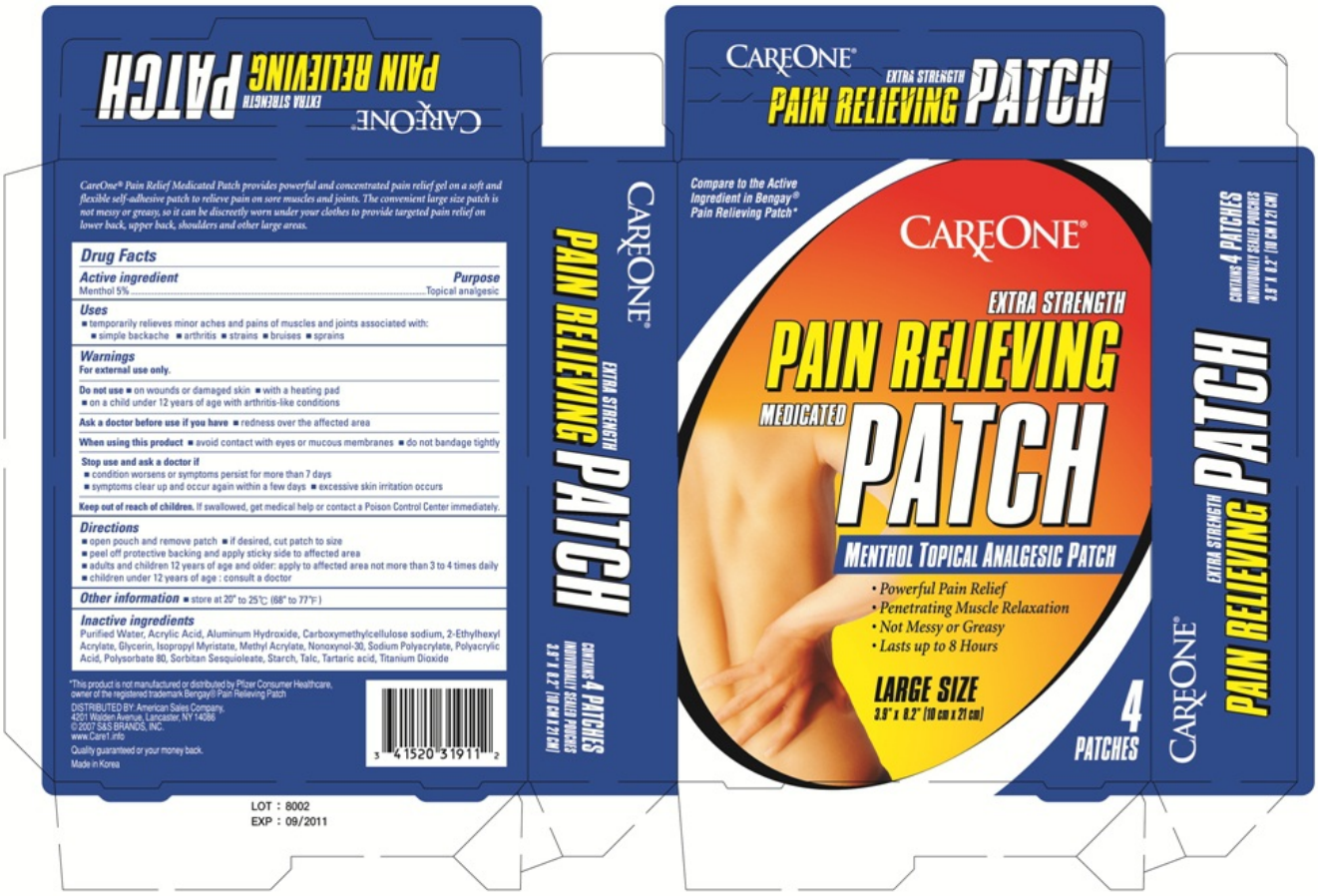
- store at 20° to 25°C (68°F to 77°F)

Inactive ingredients

Purified Water, Acrylic Acid, Aluminum Hydroxide, Carboxymethylcellulose 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

Pain Relieving Patch



MEDICATED PAIN RELIEF

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-911

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	428.5 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: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-911-04	4 in 1 CARTON		
1		1 in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/16/2011	

Labeler - American Sales Company (809183973)

Revised: 9/2011 American Sales Company