

COLD AND HOT MEDICATED- menthol patch

The Mentholatum 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

Menthol - Topical analgesic

Uses

temporarily relieves minor aches and pains of muscles and joints due to

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

Warnings

When using this product

- use only as directed
- avoid contact with eyes or on mucous membranes
- do not apply to wounds or to damaged or very sensitive skin
- do not bandage tightly or use with a heating pad

Stop use and ask a doctor if

- excessive redness or irritation is present
- condition worsens
- pain persist for more than 7 days
- symptoms 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

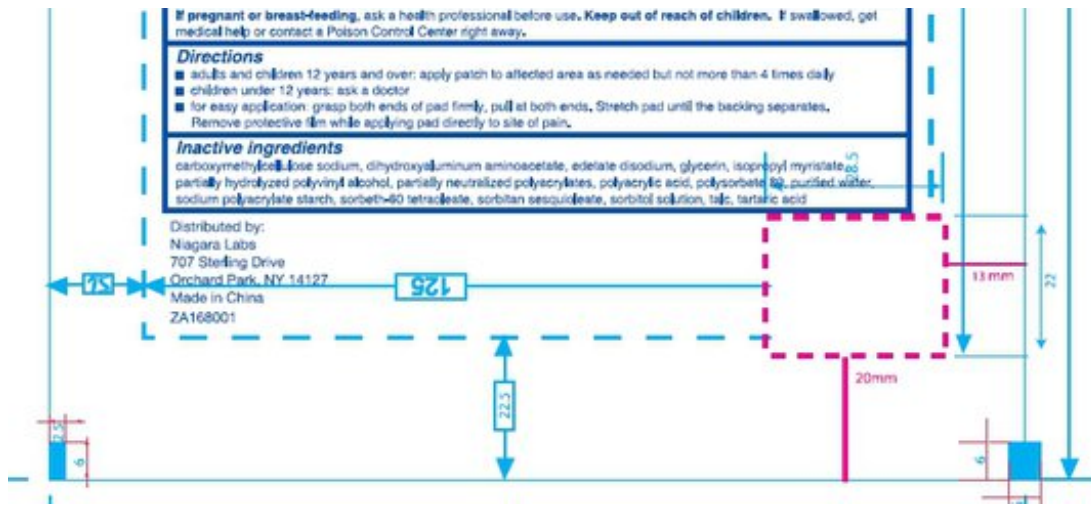
- adults and children 12 years and over: apply patch to affected area as needed but not more than 4 times daily
- children under 12 years: ask a doctor
- for easy application; grasp both ends of pad firmly, pull at both ends. Stretch pad until the backing separates. Remove protective film while applying pad directly to site of pain.

Inactive ingredients

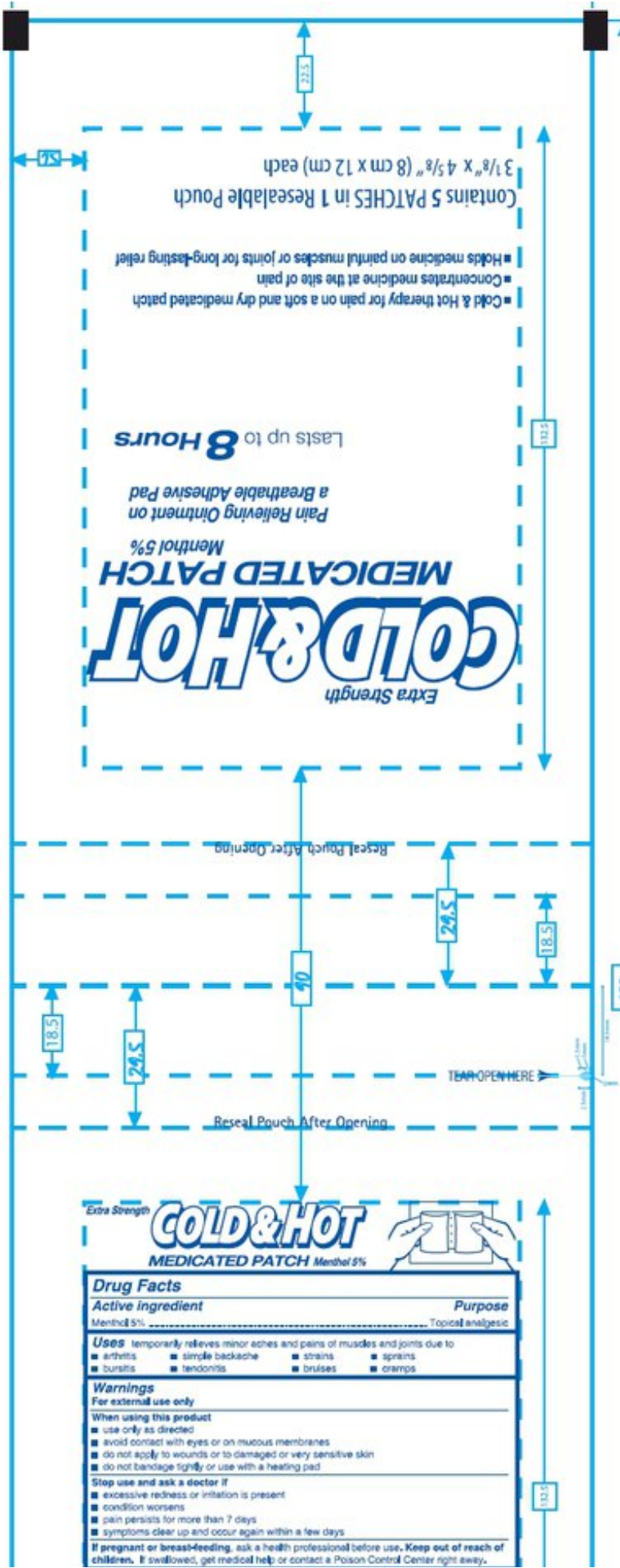
carboxymethylcellulose sodium, dihydroxyaluminum aminoacetate, edetate disodium, glycerin, isopropyl myristate, partially hydrolyzed polyvinyl alcohol, partially neutralized polyacrylates, polyacrylic acid, polysorbate 80, purified water, sodium polyacrylate starch, sorbeth-60 tetraoleate, sorbitan sesquioleate, sorbitol solution, talc, tartaric acid

Package/Label Principal Display Panel

Cold and Hot Medicated Patch Menthol 5% (Large)



Package/Label Principal Display Panel
 Cold and Hot Medicated Patch Menthol 5% (Small)

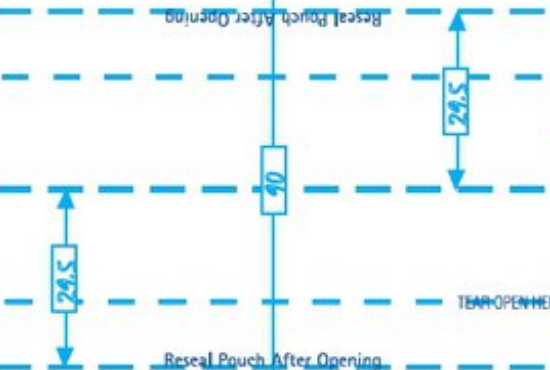


3 1/8" X 4 5/8" (8 cm X 12 cm) each
 Contains 5 PATCHES in 1 Resealable Pouch

- Cold & Hot therapy for pain on a soft and dry medicated patch
- Concentrates medicine at the site of pain
- Holds medicine on painful muscles or joints for long-lasting relief

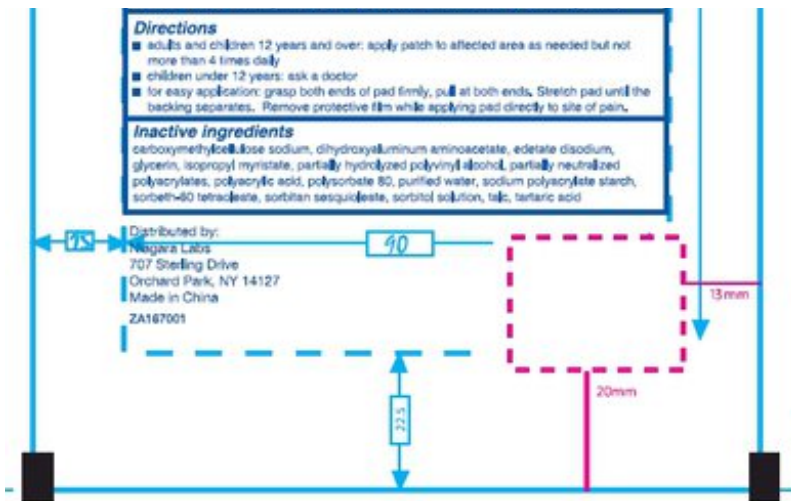
Lasts up to **8 Hours**

Extra Strength COLD & HOT MEDICATED PATCH
 Menthol 5%
 Pain Relieving Ointment on
 a Breathable Adhesive Pad



Extra Strength COLD & HOT MEDICATED PATCH Menthol 5%

Drug Facts	Purpose
Active ingredient Menthol 5%	Topical analgesic
Uses temporarily relieves minor aches and pains of muscles and joints due to	
<ul style="list-style-type: none"> ■ arthritis ■ simple backache ■ bursitis ■ tendonitis 	<ul style="list-style-type: none"> ■ strains ■ sprains ■ bruises ■ cramps
Warnings	
For external use only	
When using this product	
<ul style="list-style-type: none"> ■ use only as directed ■ avoid contact with eyes or on mucous membranes ■ do not apply to wounds or to damaged or very sensitive skin ■ do not bandage tightly or use with a heating pad 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> ■ excessive redness or irritation is present ■ condition worsens ■ pain persists for more than 7 days ■ symptoms 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.	



COLD AND HOT MEDICATED

menthol patch

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:10742-8117
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (MENTHOL)	MENTHOL	50 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM	
DIHYDROXYALUMINUM AMINO ACETATE	
EDETATE DISODIUM	
GLYCERIN	
ISOPROPYL MYRISTATE	
POLYVINYL ALCOHOL	
POLYACRYLIC ACID (250000 MW)	
POLYSORBATE 80	
WATER	
SORBITAN SESQUIOLEATE	
SORBITOL	
TALC	
TARTARIC ACID	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-8117-1	5 in 1 POUCH		

2 | NDC:10742-8117-2 | 5 in 1 POUCH

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/10/2008	

Labeler - The Mentholatum Company (002105757)

Revised: 4/2013

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