COLD/HOT MEDICATED PATCHES- medicated patches patch
Dynarex Corporation

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.

1451 - NDC 67777-145-10
1452 - NDC 67777-145-20
1453 - NDC 67777-145-30

Active ingredient

Menthol 5%

Purpose

Topical analgesic

Use

Temporarily relieves minor aches and pains of muscles and joints due to arthritis, simple backache, strains, sprains, bruises

Warnings

For external use only

Do not use

on wounds or damaged skin, with a heating pad, if you are allergic to any ingredients of this product

When using this product

use only as directed, avoid contact with the eyes, mucous membranes or rashes

Stop use and ask a doctor if

- excessive redness or irritation is present
- conditions worsen
- symptoms 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.

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

Directions

Adults and children 12 years of age and over

- clean and dry affected area
- remove film from patch and apply to the skin
- apply 1 patch at a time to affected area, not more than 3 to 4 times daily
- wear each patch up to 8 hours maximum

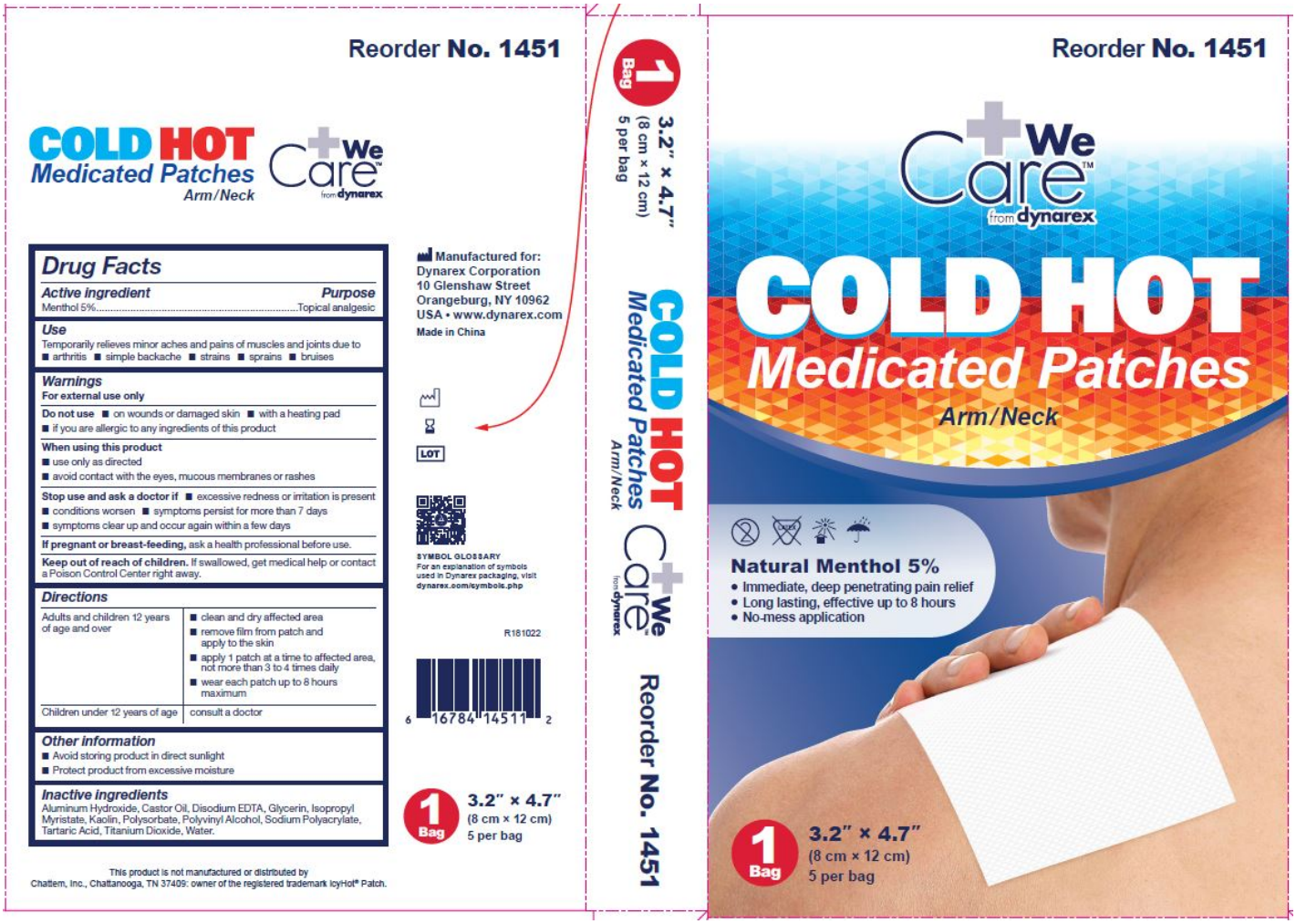
Children under 12 years of age
- consult a doctor

Other information
- Avoid storing product in direct sunlight
- Protect product from excessive moisture

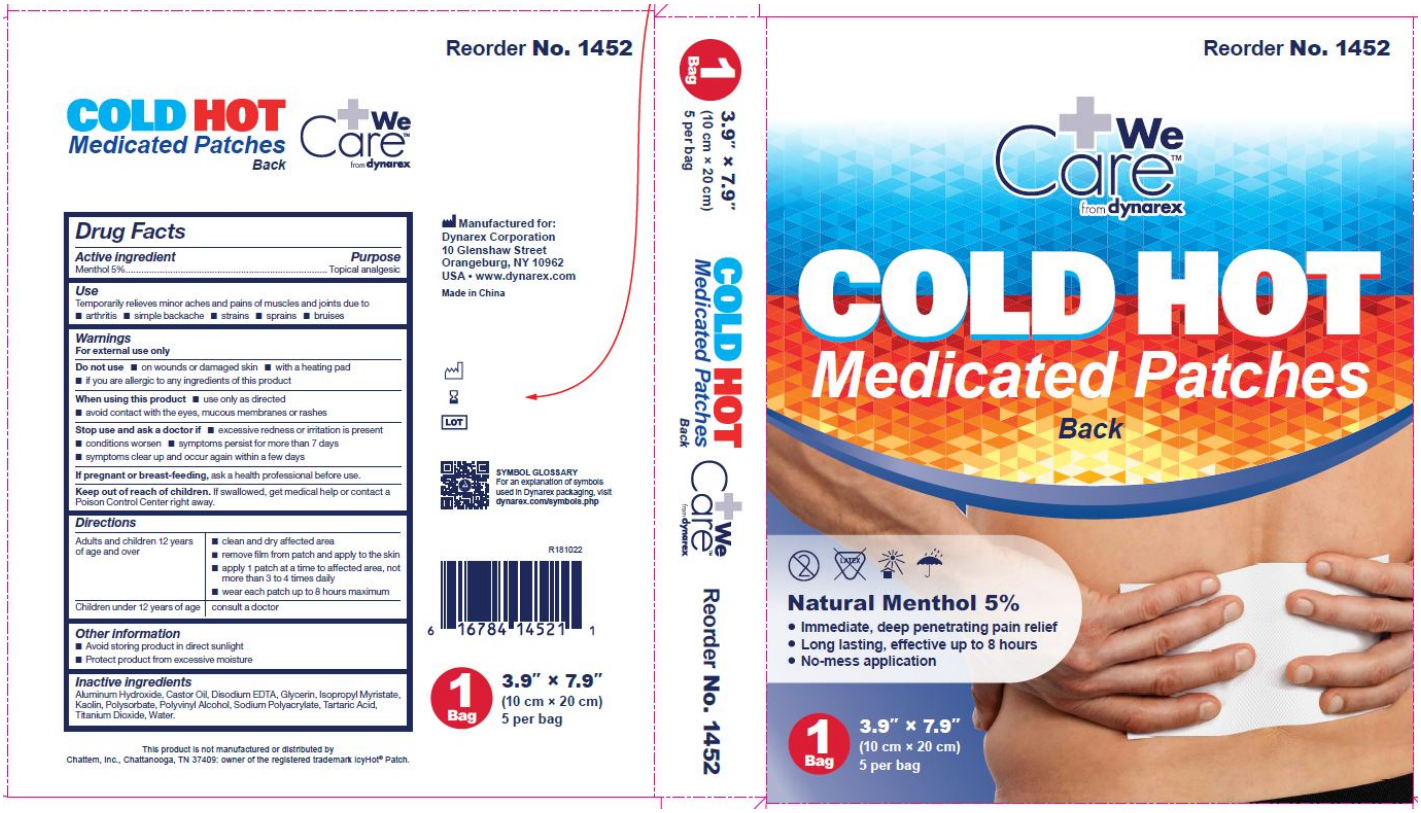
Inactive ingredients

Aluminum Hydroxide, Castor Oil, Disodium EDTA, Glycerin, Isopropyl Myristate, Kaolin, Polysorbate, Polyvinyl Alcohol, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water.

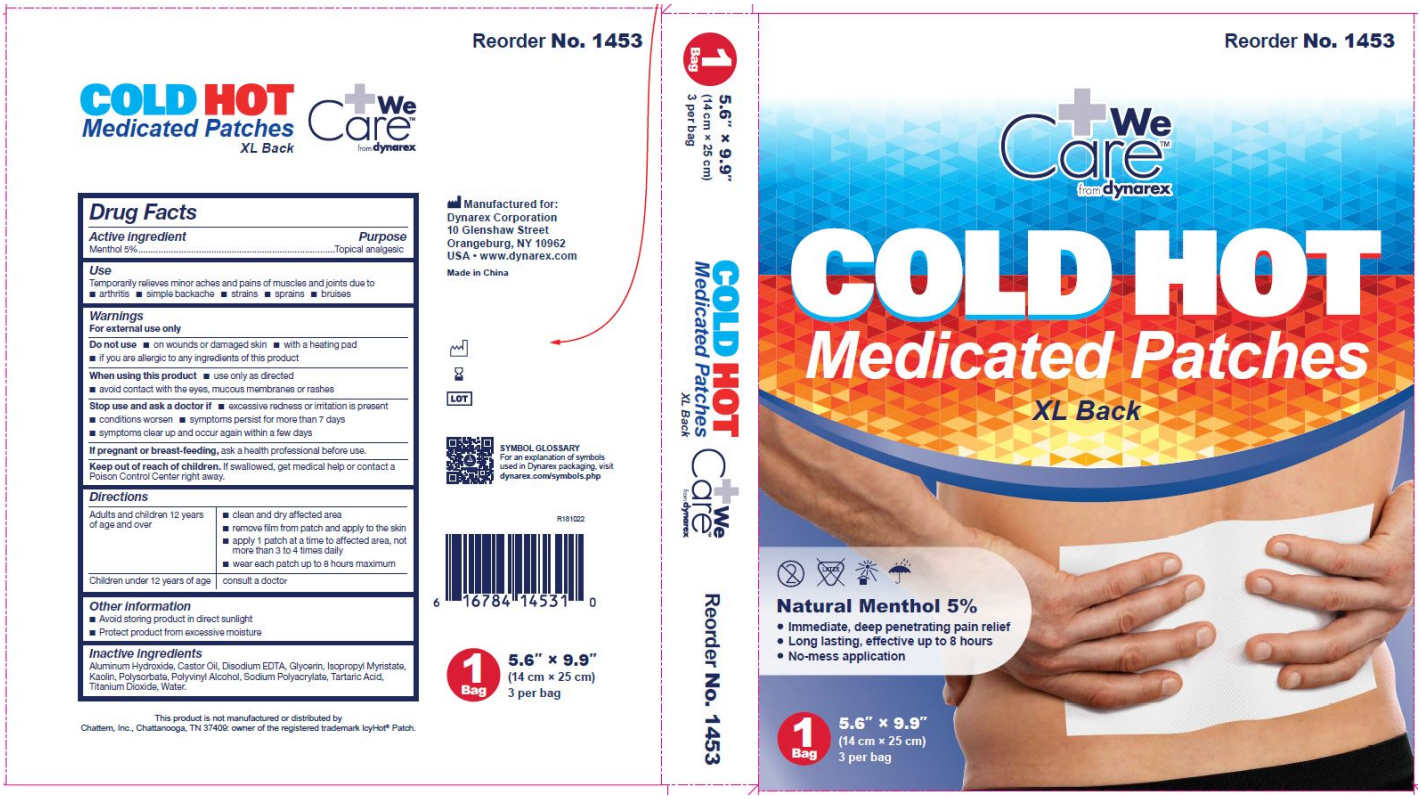
Label NDC 67777-145-10



Label NDC 67777-145-20



Label NDC 67777-145-30



COLD/HOT MEDICATED PATCHES

medicated patches patch

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-145
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 5 mg

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TARTARIC ACID (UNII: W4888I119H)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
CASTOR OIL (UNII: D5340Y2I9G)	
KAOLIN (UNII: 24H4NWX5CO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-145-10	180 in 1 CASE	08/15/2018	
1		5 in 1 BOX		
1		5 mg in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:67777-145-20	180 in 1 CASE	08/15/2018	
2		5 in 1 BOX		
2		5 mg in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:67777-145-30	108 in 1 CASE	08/15/2018	
3		3 in 1 BOX		
3		5 mg 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	08/15/2018	

Labeler - Dynarex Corporation (008124539)

Revised: 11/2018 Dynarex Corporation