# HOT/COLD MEDICATED PATCH- hot cold patch patch Dynarex

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.

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#### 1451 Cold/Hot Medictaed Patches Arm/Neck 67777-201-10 1452 Cold/Hot Medicated Patches Back 67777-201-20

#### 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
- sypmtoms 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 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

Dihydroxyaluminum Aminoacetate, Glycerin, Kaolin, Methylparaben, Polyacrylic Acid, Polysorbate 80, Propylene Glycol, Propylparaben, PVP, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water

#### Reorder No. 1451 Reorder No. 1451 Reorder No. 1451 3.2" × 4.7" (8 cm × 12 cm) 5 per bag Ve COLD HOT We **Medicated Patches** are Arm/Neck am dynarex Manufactured for: Dynarex Corporation 10 Glenshaw Street Orangeburg, NY 10962 USA • www.dynarex.co **Drug Facts** OLD<sup>®</sup> Active ingredient Purpose Medicated Pa G Use Made In China Temporarily relieves minor aches and pains of muscles and joints due to arthritis simple backache strains sprains bruises Medicated Patches Warnings For external use only 2 Arm/Neck Do not use on wounds or damaged skin with a heating pad If you are allergic to any ingredients of this product Medicated Patches R When using this product LOT tches use only as directed avoid contact with the eyes, mucous membranes or rashes /Nect Stop use and ask a doctor If excessive redness or irritation is pr conditions worsen e symptoms persist for more than 7 days symptoms clear up and occur again within a few days 0 🛛 🗑 券 🗲 If pregnant or breast-feeding, ask a health professional bef Keep out of reach of chilidren. If swallowed, get medical help or contac a Poison Control Center right away. **Natural Menthol 5%** $\Omega$ Immediate, deep penetrating pain relie Long lasting, effective up to 8 hours Directions Ĩ. € clean and dry affected area remove film from patch and apply to the skin apply 1 patch at a time to affect not more than 3 to 4 times daily Adults and children 12 years of age and over No-mess application Reorder No. wear each patch up to 8 hours maximum **3.2'' × 4.7''** (8 cm × 12 cm) 5 per bag Children under 12 years of age consult a doctr Other information Avoid storing product in direct sunlight Protect product from excessive moistu Inactive ingredients droxyaluminum Aminoacetale, Glycerin, Kaolin, Methylparab crylic Acid, Polysorbate 80, Propylene Glycol, Propylparab Sodium Polyacrylale, Tartaric Acid, Titanium Dioxide, Water 3.2" × 4.7" (8 cm × 12 cm) 1451 3.2" × 4.7' 5 per bag 1 (8 cm × 12 cm) 5 per bag This product is not manufactured or distributed by Chattern, Inc., Chattanooga, TN 37409: owner of the registered trademark lcyHot<sup>a</sup> Patch R191202

#### Label



#### HOT/COLD MEDICATED PATCH hot cold patch patch **Product Information** HUMAN OTC DRUG NDC:67777-201 **Product Type** Item Code (Source) **Route of Administration** TOPICAL **Active Ingredient/Active Moiety** Ingredient Name **Basis of Strength** Strength MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) MENTHOL 285 mg in 5700 mg **Inactive Ingredients** Ingredient Name Strength KAOLIN (UNII: 24H4NWX5CO) PROPYLPARABEN (UNII: Z8IX2SC1OH) DIHYDRO XYAL UMINUM AMINO ACETATE (UNII: DO 250 MG0 W6) TARTARIC ACID (UNII: W48881119H) POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) POVIDONE (UNII: FZ989GH94E) SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L) TITANIUM DIO XIDE (UNII: 15FIX9V2JP)

GLYCERIN (UNII: PDC6A3C0OX) METHYLPARABEN (UNII: A218C7HI9T)

WATER (UNII: 059QF0KO0R)

DO		UNII: 6 O Z P 39 Z G 8 H)		
PU	LISORDALE 80 (	UNII: 602P392G8H)		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-201-10	180 in 1 CASE	12/13/2019	
1		5 in 1 BOX		
1		285 mg in 1 PATCH; Type 0: Not a Combination Product		
<b>2</b> ľ	NDC:67777-201-20	180 in 1 CASE	12/13/2019	
2		5 in 1 BOX		
2		285 mg in 1 PATCH; Type 0: Not a Combination Product		
M	arketing Inf	ormation		
Marketing Category		ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not fin		nal part348	12/13/2019	

## Labeler - Dynarex (008124539)

**Registrant** - Dynarex (008124539)

Revised: 12/2019

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