

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

Reorder No. 1451

COLD HOT Medicated Patches Arm/Neck **Care+We** from **dynarex**

1 Bag 3.2" x 4.7" (8 cm x 12 cm) 5 per bag

Drug Facts

Active ingredient	Purpose
Menthol 5%	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
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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.

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
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Manufactured for: Dynarex Corporation, 10 Glenshaw Street, Orangeburg, NY 10962, USA • www.dynarex.com, Made in China

SYMBOL GLOSSARY
For an explanation of symbols used in Dynarex packaging, visit dynarex.com/symbols.php

Natural Menthol 5%
• Immediate, deep penetrating pain relief
• Long lasting, effective up to 8 hours
• No-mess application

1 Bag 3.2" x 4.7" (8 cm x 12 cm) 5 per bag

Reorder No. 1451

This product is not manufactured or distributed by Chatten, Inc., Chattanooga, TN 37409; owner of the registered trademark IcyHot® Patch.

Label NDC 67777-145-20

COLD HOT
Medicated Patches



Reorder No. 1452

Drug Facts

Active ingredient	Purpose
Menthol 5%	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	
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 10 Glenshaw Street
 Orangeburg, NY 10962
 USA • www.dynarex.com
 Made in China



1 Bag 3.9" x 7.9"
 (10 cm x 20 cm)
 5 per bag

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 Chatten, Inc., Chattanooga, TN 37409; owner of the registered trademark **kyHot**® Patch.

1 Bag 3.9" x 7.9"
 (10 cm x 20 cm)
 5 per bag

COLD HOT
 Medicated Patches
 Back



Reorder No. 1452

Reorder No. 1452



COLD HOT
 Medicated Patches

Back



Natural Menthol 5%

- Immediate, deep penetrating pain relief
- Long lasting, effective up to 8 hours
- No-mess application

1 Bag 3.9" x 7.9"
 (10 cm x 20 cm)
 5 per bag

Label NDC 67777-145-30

COLD HOT
 Medicated Patches



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 Made in China



1 Bag 5.6" x 9.9"
 (14 cm x 25 cm)
 3 per bag

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1 Bag 5.6" x 9.9"
 (14 cm x 25 cm)
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COLD HOT
 Medicated Patches
 XL Back



Reorder No. 1453

Reorder No. 1453



COLD HOT
 Medicated Patches

XL Back



Natural Menthol 5%

- Immediate, deep penetrating pain relief
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1 Bag 5.6" x 9.9"
 (14 cm x 25 cm)
 3 per bag

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: W4888119H)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	SODIUM POLYACRYLATE (2500000 MW) (UNII: 05115JN12J)			
	ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)			
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
	WATER (UNII: 059QF0K00R)			
	CASTOR OIL (UNII: D5340Y219G)			
	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)