

ASSURED COLD N HOT PAIN RELIEF MENTHOL- menthol patch
Greenbrier International, Inc

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.

Assured Cold'n Hot Medicated Patch 2ct 6159, 2020

Active Ingredient	Purpose
Menthol 5%-----	Topical analgesic

Uses

Temporarily relieves minor pains associated with:

- arthritis
- simple backache
- bursitis
- tendonitis
- muscle strains
- muscle cramps

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 use if you have

- redness over the affected area

When using this product

- use as only directed
- avoid contact with eyes and mucous membranes
- do not bandage tightly
- discontinue use at least 1 hour before a bath or shower
- do not use immediately after a bath or shower

Stop use and ask a doctor if

- condition worsens or symptoms persist more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

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 (1-800-222-1222) right away.

Directions

- open pouch and remove patch
- carefully peel off protective packing and apply sticky side to affected area
- adults and children 12 years of age and older:
- do not wear patch for more than 8 hours

- apply to affected area no more than 3 times daily
- children under 12 years of age: consult a doctor

Other information

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

Inactive ingredients

aloe vera, aluminum hydroxide, BHT, castor oil, concentrated glycerin, disodium edetate hydrate, dried aluminum hydroxide gel, gelatin, isopropyl myristate, kaolin, magnesium aluminosilicate, methyl paraben, peg monostearate, polysorbate 80, polyvinyl alcohol, purified water, PVP, sodium polyacrylate, tartaric dioxide, tocopherol acetate

DISTRIBUTED BY

GREENBRIER INTERNATIONAL, INC.

500 VOLVO PARKWAY

CHESAPEAKE, VA 23320

MADE IN KOREA



6159-SS-PH-R1
PR-MD-SS-101-R1

984636
DISTRIBUTED BY:
GREENBRIER INTERNATIONAL, INC.
500 VOLVO PARKWAY
CHESAPEAKE, VA 23320
MADE IN SOUTH KOREA

*This product is not manufactured or distributed by Chattem, Inc., distributor of Icy Hot® Medicated Patch.

<p>Usage facts (continued)</p>	<p>Usage facts</p>
<p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) night away.</p>	<p>Active ingredient Menthol 5%.....Topical analgesic</p>
<p>Directions</p> <ul style="list-style-type: none"> ■ open pouch and remove patch ■ carefully peel off protective backing and apply sticky side to affected area ■ adults and children 12 years of age and older: do not wear patch for more than 8 hours ■ children under 12 years of age: consult a doctor 	<p>Uses</p> <ul style="list-style-type: none"> ■ temporarily relieves minor aches and pains of muscles and joints associated with: ■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains
<p>Other information</p> <ul style="list-style-type: none"> ■ store at room temperature 20-25°C (68-77°F) 	<p>Warnings</p> <p>For external use only</p> <ul style="list-style-type: none"> ■ Do not use ■ on wounds or damaged skin ■ with a heating pad ■ on a child under 12 years of age with arthritis-like conditions
<p>Inactive ingredients aloe vera gel, BHT, castor oil, concentrated glycerin, disodium edetate hydrate, dried aluminum hydroxide gel, gelatin, isopropyl myristate, kaolin, magnesium aluminosilicate, methyl paraben, peg monostearate, polysorbate 80, polyvinyl alcohol, purified water, PVP, sodium polyacrylate, tartaric acid, titanium dioxide, tocopherol acetate</p>	<p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ redness over the affected area
<p>Questions or comments? Call 1-888-645-8204 Monday-Friday 9AM-5PM (PST)</p>	<p>When using this product</p> <ul style="list-style-type: none"> ■ use only as directed ■ avoid contact with eyes or mucous membranes ■ do not bandage tightly ■ discontinue use at least 1 hour before a bath or shower ■ do not use immediately after a bath or shower
<p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ condition worsens or symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days ■ excessive skin irritation occurs 	<p>Do not use</p> <ul style="list-style-type: none"> ■ on wounds or damaged skin ■ with a heating pad ■ on a child under 12 years of age with arthritis-like conditions



Medicated Pain Relief Patch
Arm, Neck, Leg & Small areas
Menthol 5% (Topical analgesic)

Extra Strength Cold 'n Hot

Reseal pouch after opening ←

ASSURED™

← TEAR HERE

← TEAR HERE

ASSURED™

→ Reseal pouch after opening

ASSURED™

Extra Strength

Cold 'n Hot

Medicated Pain Relief Patch
Arm Neck Leg & Small areas



ARM, NECK, LEG & OTHER AREAS
Menthol 5% (Topical analgesic)

- Use up to 8 hours
- Powerful pain relief
- Long lasting

COLD & HOT PAIN RELIEF

2 patches

Compare
to the
active ingredient in
ICY HOT®
MEDICATED PATCH*

Resealable Package
3 1/8 IN X 4 5/8 IN (8 CM X 12 CM)

ASSURED COLD N HOT PAIN RELIEF MENTHOL

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-6159
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	

CASTOR OIL (UNII: D5340Y2I9G)
EDETATE DISODIUM (UNII: 7FLD91C86K)
GELATIN (UNII: 2G86QN327L)
GLYCERIN (UNII: PDC6A3C0OX)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
KAOLIN (UNII: 24H4NWX5CO)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
METHYL PARABEN (UNII: A2I8C7H9T)
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
POLYVINYL ALCOHOL (UNII: 532B59J990)
WATER (UNII: 059QF0K00R)
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)
TARTARIC ACID (UNII: W4888I119H)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-6159-5	2 in 1 PACKET	10/17/2014	
1		5 mg in 1 POUCH; 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	10/17/2014	

Labeler - Greenbrier International, Inc (610322518)

Revised: 10/2020

Greenbrier International, Inc