

3% MENTHOL PLUS 0.083% CAPSAICIN PAIN RELIEF PATCH (2 PATCHES/POUCH) - pain relief patch, pain relief strip patch
5% MENTHOL PAIN RELIEF PATCH (1 LARGE PATCH/POUCH)- pain relief patch patch
5% MENTHOL PAIN RELIEF PATCH (2 PATCHES/POUCH) - pain relief patch patch
0.025% CAPSAICIN PATCH (2 PATCHES/POUCH) 82632- capsaicin pain relief patch, capsaicin pain relief strip patch
Koolcare Technology Co., Ltd

0.025% Capsaicin Patch (2 Patches/Pouch) NDC: 84205-005-00



Uses

Topical Analgesic

For temporary relief of minor aches and pains of muscles & joints associated with:

- Simple Backache
- Arthritis
- Strains
- Bruises
- Sprains

Warnings

WARNINGS: EXTERNAL USE ONLY

DO NOT USE

- on wounds or damaged skin
- with a heating pad
- with or at the same times as other external analgesic
- if you are allergic to any ingredients of this product

When using this product

- do not use otherwise than as directed
- avoid contact with the eyes, mucous membranes or rashes
- 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

- rash, itching or excessive skin irritation develops
- conditions worsen
- symptoms persist for more than 7 days
- symptoms clear up and occur again with 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 (1-800-222-1222) immediately.

Inactive Ingredients

Glycerin, Sodium Polyacrylate, Dihydroxyaluminium Aminoacetate Anhydrous, Edetate Disodium, Kaolin, Propylene Glycol, Polysorbate 80, Carboxymethylcellulose Sodium, Carbomer, Purified Water, POVIDONE K90, Tartaric Acid, DMDM Hydantoin

Directions

DIRECTIONS

Adults and Children 12 years of age and older:

- Clean and dry affected area
- Remove patch from film
- Apply to affected area not more than 3 to 4 times daily
- Remove patch from skin after at most 8 hours of application

Children under 12 years of age: Consult a doctor.

Purpose

TOPICAL ANALGESIC

Warnings

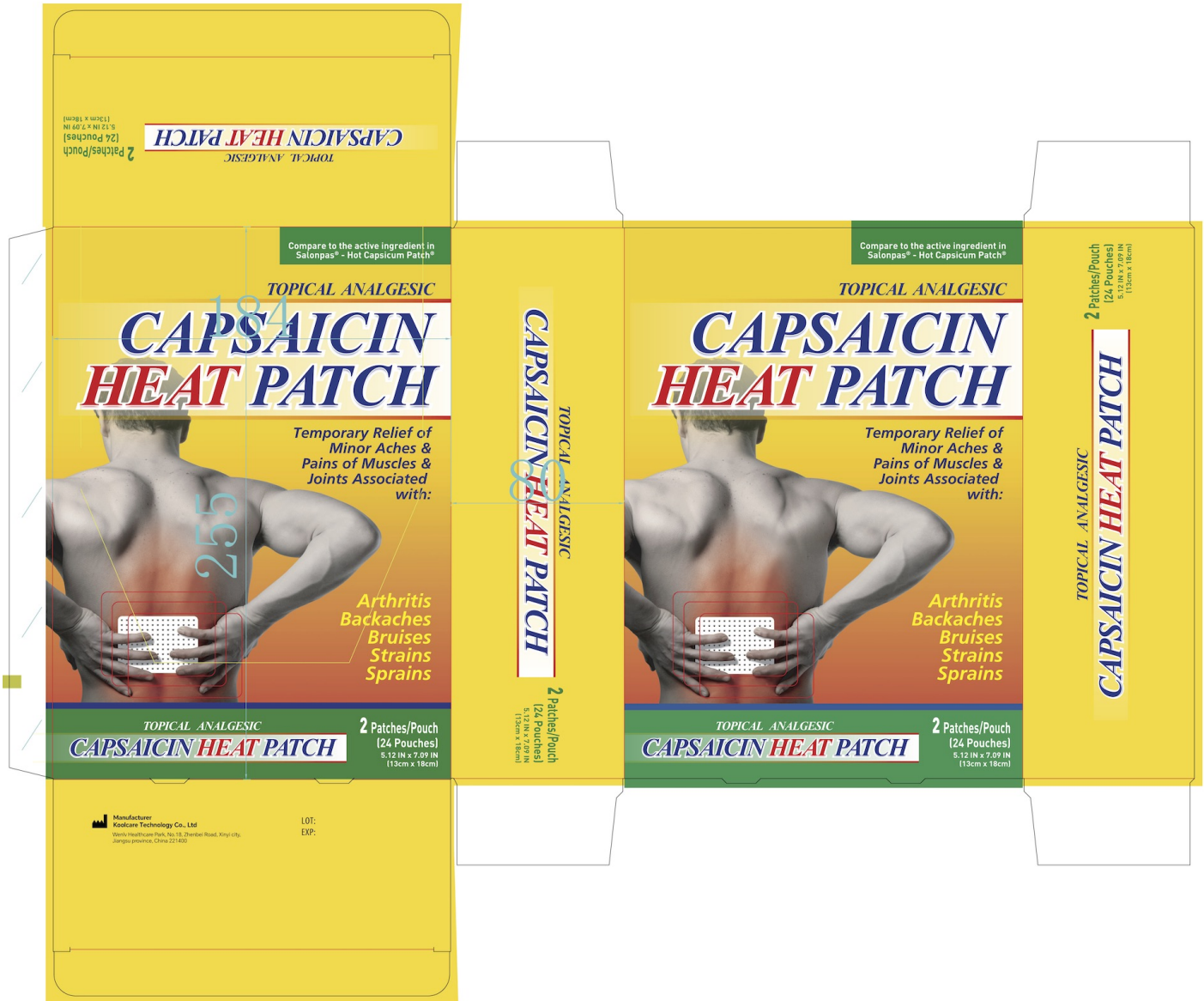
KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a

Poison Control Center (1-800-222-1222) immediately.

0.025% Capsaicin Patch (24 Pouches/Box) NDC: 84205-005-01

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Uses

Topical Analgesic

For temporary relief of minor aches and pains of muscles & joints associated with:

- Simple Backache
- Arthritis
- Strains
- Bruises
- Sprains

Warnings

WARNINGS: EXTERNAL USE ONLY

DO NOT USE

- on wounds or damaged skin
- with a heating pad
- with or at the same times as other external analgesic
- if you are allergic to any ingredients of this product

When using this product

- do not use otherwise than as directed
- avoid contact with the eyes, mucous membranes or rashes
- 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

- rash, itching or excessive skin irritation develops
- conditions worsen
- symptoms persist for more than 7 days
- symptoms clear up and occur again with few days

If pregnant or breast-feeding, ask a health professional before use.

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Inactive Ingredients

Glycerin, Sodium Polyacrylate, Dihydroxyaluminium Aminoacetate Anhydrous, Edetate Disodium, Kaolin, Propylene Glycol, Polysorbate 80, Carboxymethylcellulose Sodium, Carbomer, Purified Water, POVIDONE K90, Tartaric Acid, DMDM Hydantoin

Directions

DIRECTIONS

Adults and Children 12 years of age and older:

- Clean and dry affected area
- Remove patch from film
- Apply to affected area not more than 3 to 4 times daily
- Remove patch from skin after at most 8 hours of application

Children under 12 years of age: Consult a doctor.

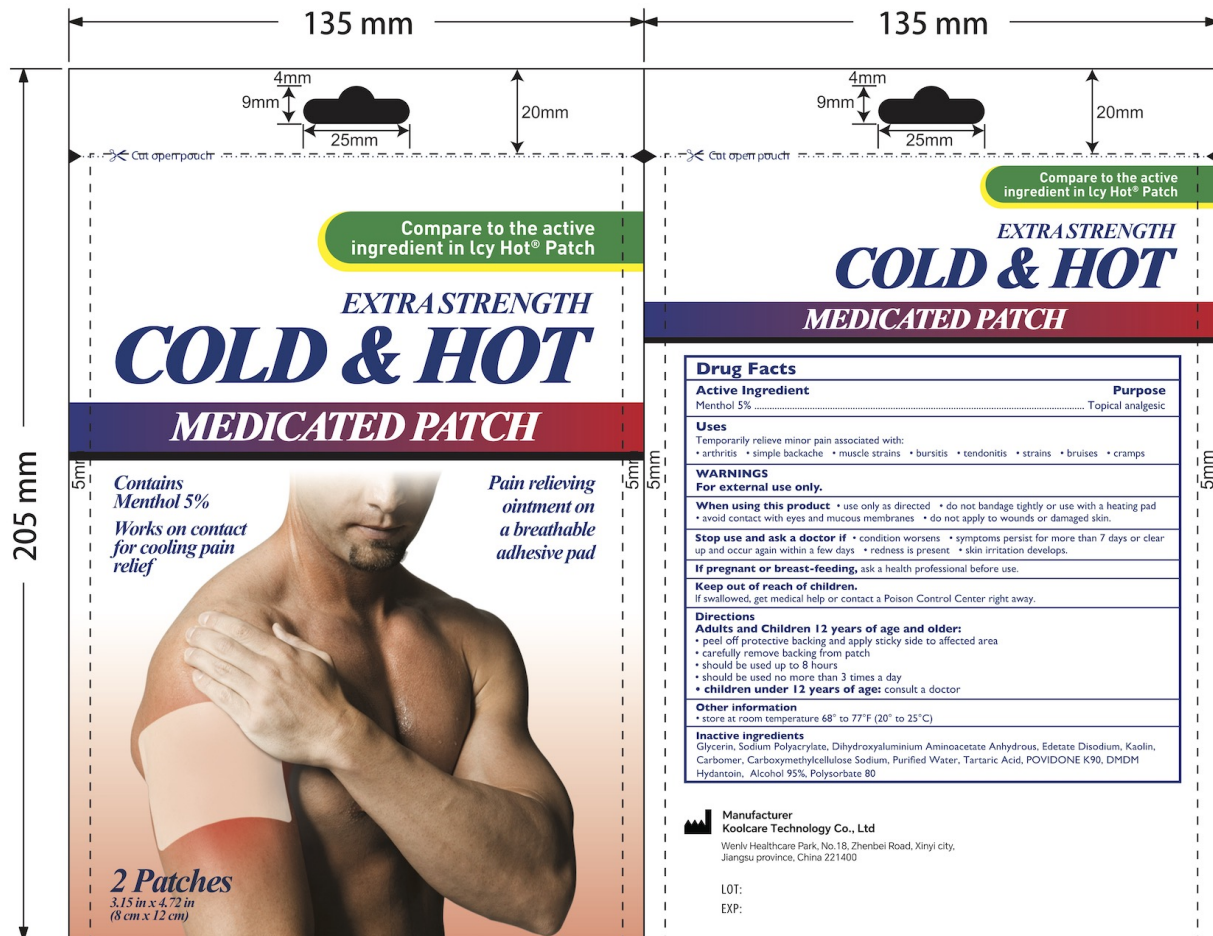
Purpose

TOPICAL ANALGESIC

Warnings

KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

5% Menthol Pain Relief Patch (2 Patches/Pouch) NDC: 84205-006-00



Uses

Topical Analgesic

Temporary relieve minor pain associated with:

- Arthritis
- Simple Backache
- Muscle Strains
- Bursitis
- Tendonitis
- Strains
- Bruises
- Cramps

Warnings

WARNINGS

For external use only.

When using this product

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

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present
- skin irritation develops.

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.

Inactive Ingredients

Glycerin, Sodium Polyacrylate, Dihydroxyaluminium Aminoacetate Anhydrous, Edetate Disodium, Kaolin, Carbomer, Carboxymethylcellulose Sodium, Purified Water, Tartaric Acid, POVIDONE K90, DMDM Hydantoin, Alcohol 95%, Polysorbate 80

Directions

Directions

Adults and Children 12 years of age and older:

- Peel off protective backing and apply sticky side to affected area.
- Carefully remove backing from patch
- Should be used up to 8 hours
- Should be used no more than 3 times a day
- **Children under 12 years of age:** Consult a doctor.

Purpose

Topical Analgesic

Warnings

Keep out of reach of children.

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

5% Menthol Pain Relief Patch (24 Pouches/Box) NDC: 84205-006-01

140x80x210mm

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Uses

Topical Analgesic
Temporary relieve minor pain associated with:

- Arthritis
- Simple Backache
- Muscle Strains
- Bursitis
- Tendonitis
- Strains
- Bruises

- Cramps

Warnings

WARNINGS

For external use only.

When using this product

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

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present
- skin irritation develops.

If pregnant or breast-feeding, ask a health professional before use.

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Inactive Ingredients

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Adults and Children 12 years of age and older:

- Peel off protective backing and apply sticky side to affected area.
- Carefully remove backing from patch
- Should be used up to 8 hours
- Should be used no more than 3 times a day
- **Children under 12 years of age:** Consult a doctor.

Purpose

Topical Analgesic

Warnings

Keep out of reach of children.

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

3% Menthol plus 0.083% Capsaicin Pain Relief Patch (2 Patches/Pouch) NDC: 84205-007-00



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Uses

Topical Analgesic

Temporarily relieves minor pain associated with:

- Arthritis
- Simple Backache
- Bursitis
- Tendonitis
- Muscle Strains
- Bruises
- Cramps

Warnings

WARNINGS: EXTERNAL USE ONLY

When using this product

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

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present
- skin irritation develops.

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) immediately.

Inactive Ingredients

Glycerin, Sodium Polyacrylate, Dihydroxyaluminium Aminoacetate Anhydrous, Edetate Disodium, Kaolin, Carbomer, Carboxymethylcellulose Sodium, Purified Water, Tartaric Acid, POVIDONE K90, DMDM Hydantoin, Alcohol 95%, Polysorbate 80, Propylene Glycol

Directions

DIRECTIONS

Adults and Children 12 years of age and older:

- Partially peel back protective film and apply exposed patch to site of pain. Carefully remove remaining film while pressing patch to skin for secure adhesions
- Apply to affected area not more than 3 to 4 times daily

Children under 12 years of age: DO NOT use without consulting a doctor.

Purpose

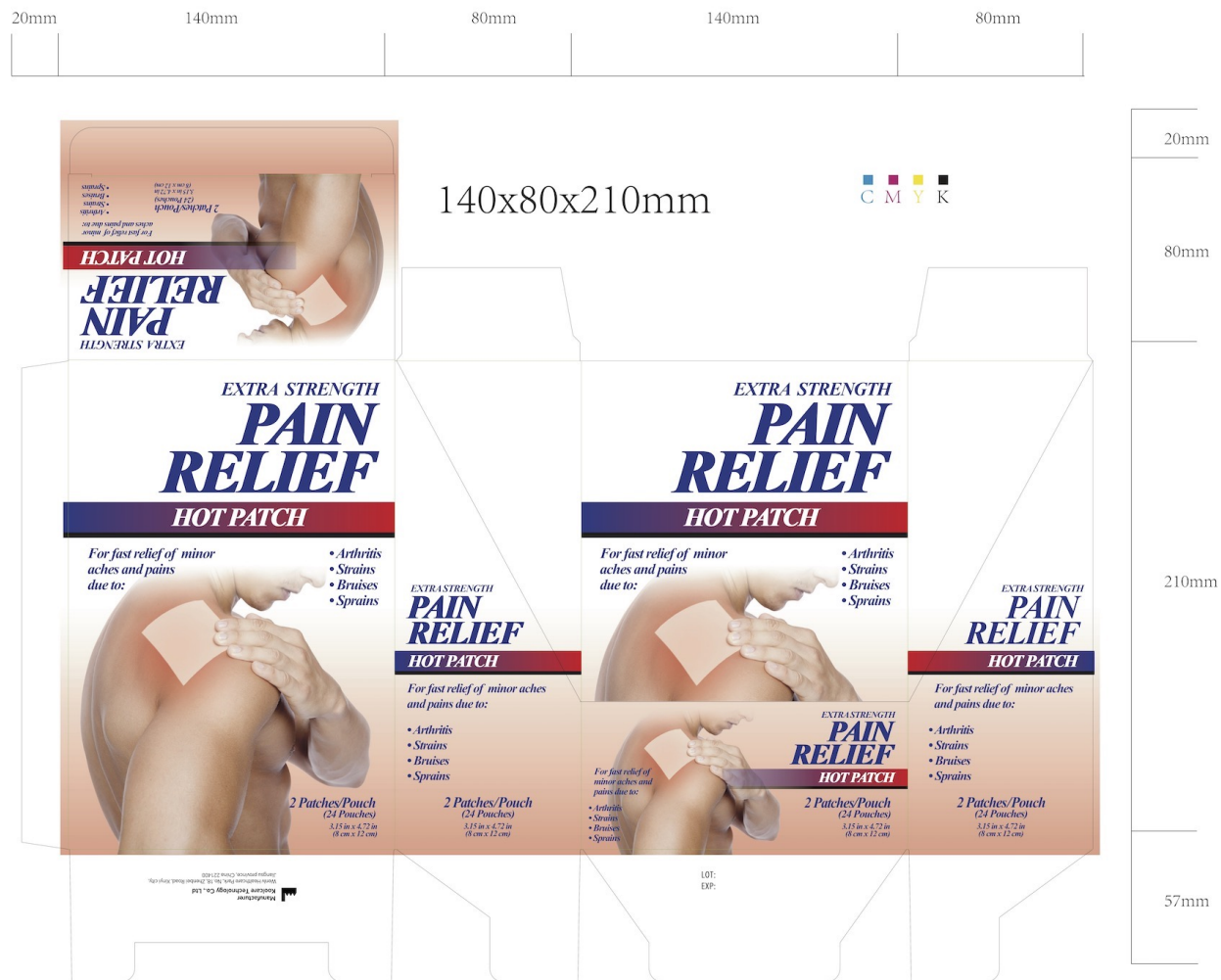
Topical Analgesic

Warnings

KEEP OUT OF REACH OF CHILDREN.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

3% Menthol plus 0.083% Capsaicin Pain Relief Patch (24 Pouches/Box) NDC: 84205-007-01



Uses

Topical Analgesic

Temporarily relieves minor pain associated with:

- Arthritis
- Simple Backache
- Bursitis
- Tendonitis
- Muscle Strains
- Bruises
- Cramps

Warnings

WARNINGS: EXTERNAL USE ONLY

When using this product

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

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present
- skin irritation develops.

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) immediately.

Inactive Ingredients

Glycerin, Sodium Polyacrylate, Dihydroxyaluminium Aminoacetate Anhydrous, Edetate Disodium, Kaolin, Carbomer, Carboxymethylcellulose Sodium, Purified Water, Tartaric Acid, POVIDONE K90, DMDM Hydantoin, Alcohol 95%, Polysorbate 80, Propylene Glycol

Directions

DIRECTIONS

Adults and Children 12 years of age and older:

- Partially peel back protective film and apply exposed patch to site of pain. Carefully remove remaining film while pressing patch to skin for secure adhesions
- Apply to affected area not more than 3 to 4 times daily

Children under 12 years of age: DO NOT use without consulting a doctor.

Purpose

Topical Analgesic

Warnings

KEEP OUT OF REACH OF CHILDREN.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

5% Menthol Pain Relief Patch (1 Large Patch/Pouch) NDC: 84205-008-00

135 mm

135 mm

4mm

9mm

25mm

20mm

4mm

9mm

25mm

20mm

*Compare to the active ingredient in Icy Hot® Patch

EXTRA STRENGTH COLD & HOT

MEDICATED PATCH

FAST RELIEF OF MINOR ACHES AND PAINS

Drug Facts

Active Ingredient	Purpose
Menthol 5%	Topical Analgesic

Uses
Temporarily relieve minor aches and pains of muscles and joints due to
• simple backache • arthritis • muscle strains • bursitis • tendonitis • muscle sprains • bruises • cramps

WARNINGS: EXTERNAL USE ONLY

When using this product
• USE ONLY AS DIRECTED • do not bandage tightly or use with a heating pad
• avoid contact with eyes and mucous membranes • do not apply to wounds or damaged skin.

STOP USE and ask a doctor if
• condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days • redness is present • skin irritation develops

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) immediately.

DIRECTIONS
Adults and Children 12 years of age and older:
• Peel off protective backing and apply sticky side to affected area. Carefully remove backing from patch
• Should be used up to 8 hours
• Should be used no more than 3 to 4 times daily
Children under 12 years of age: Consult a doctor.

Other Information
• store at room temperature 68° to 77°F (20° to 25°C)

Inactive Ingredients
Glycerin, Sodium Polysacrylate, Dihydroxyaluminum Aminoacetate Anhydrous, Edetate Disodium, Kaolin, Carbomer, Carboxymethylcellulose Sodium, Purified Water, Tartaric Acid, POVIDONE K90, DMDM Hydantoin, Alcohol 95%, Polysorbate 80

Manufacturer
Koolcare Technology Co., Ltd
Wenlv Healthcare Park, No.18, Zhenbei Road, Xinyi city, Jiangsu province, China 221400

LOT:
EXP:

205 mm

5mm

5mm

5mm

5mm

Contains Menthol 5%

Pain relieving ointment on a breathable adhesive pad

1 Large Patch
3.94 in x 7.87 in
(10 cm x 20 cm)

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Uses

Topical Analgesic

Temporarily relieve minor aches and pains of muscles and joints due to

- Simple Backache
- Arthritis
- Muscle Strains
- Bursitis
- Tendonitis
- Muscle Sprains
- Bruises
- Cramps

Warnings

WARNINGS: EXTERNAL USE ONLY

When using this product

- USE ONLY AS DIRECTED
- do not bandage tightly or use with a heating pad
- avoid contact with eyes and mucous membranes

- do not apply to wounds or damaged skin.

STOP USE and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present
- skin irritation develops

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) immediately.

Inactive Ingredients

Glycerin, Sodium Polyacrylate, Dihydroxyaluminium Aminoacetate Anhydrous, Edetate Disodium, Kaolin, Carbomer, Carboxymethylcellulose Sodium, Purified Water, Tartaric Acid, POVIDONE K90, DMDM Hydantoin, Alcohol 95%, Polysorbate 80

Directions

DIRECTIONS

Adults and Children 12 years of age and older:

- Peel off protective backing and apply sticky side to affected area. Carefully remove backing from patch
- Should be used up to 8 hours
- Should be used no more than 3 to 4 times daily

Children under 12 years of age: Consult a doctor.

Purpose

Topical Analgesic

Warnings

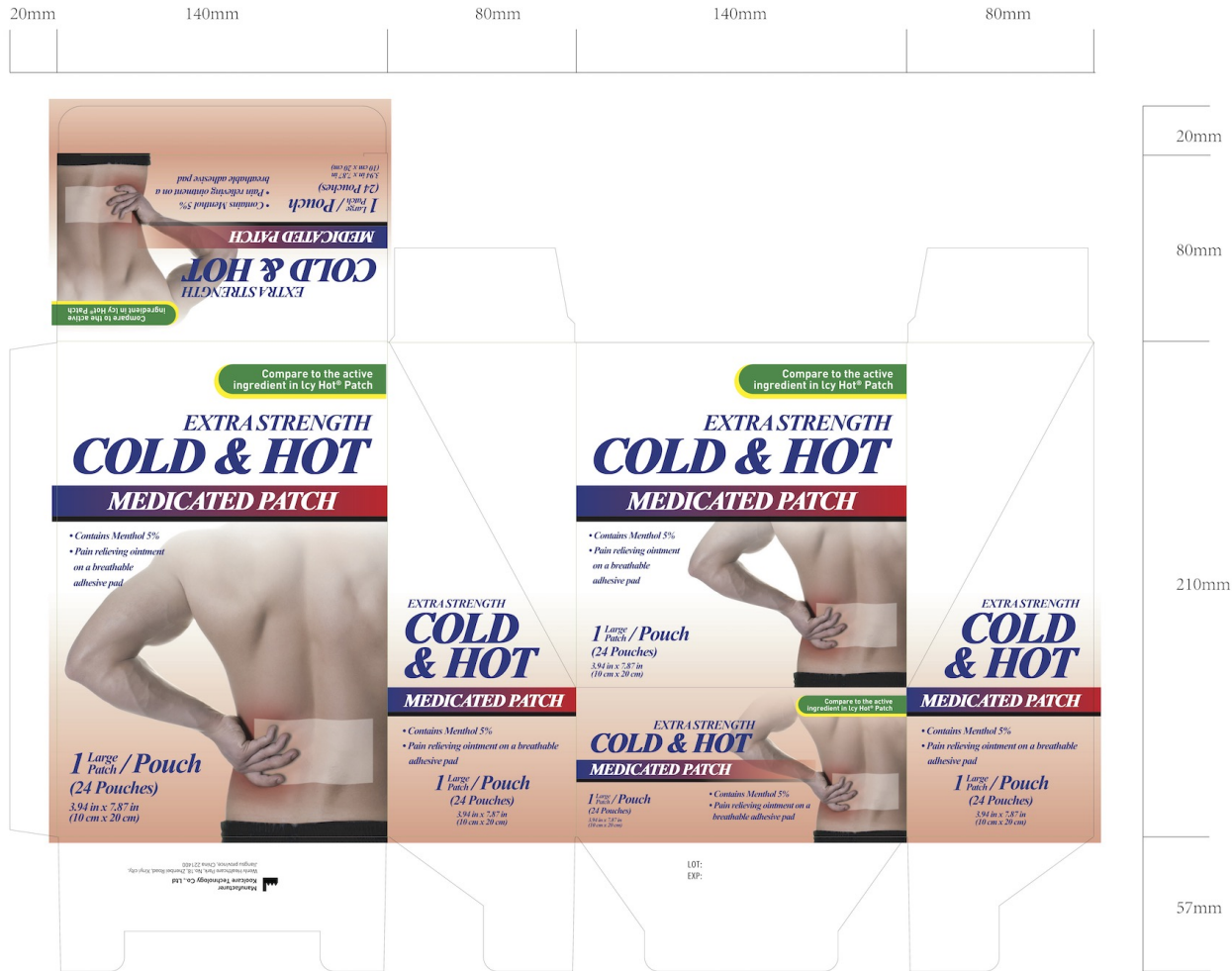
KEEP OUT OF REACH OF CHILDREN.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

5% Menthol Pain Relief Patch (1 Large Patch X 24Patches) NDC: 84205-008-01

140x80x210mm

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Uses

Topical Analgesic

Temporarily relieve minor aches and pains of muscles and joints due to

- Simple Backache
- Arthritis
- Muscle Strains
- Bursitis
- Tendonitis
- Muscle Sprains
- Bruises
- Cramps

Warnings

WARNINGS: EXTERNAL USE ONLY

When using this product

- USE ONLY AS DIRECTED
- do not bandage tightly or use with a heating pad

- avoid contact with eyes and mucous membranes
- do not apply to wounds or damaged skin.

STOP USE and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present
- skin irritation develops

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) immediately.

Inactive Ingredients

Glycerin, Sodium Polyacrylate, Dihydroxyaluminium Aminoacetate Anhydrous, Edetate Disodium, Kaolin, Carbomer, Carboxymethylcellulose Sodium, Purified Water, Tartaric Acid, POVIDONE K90, DMDM Hydantoin, Alcohol 95%, Polysorbate 80

Directions

DIRECTIONS

Adults and Children 12 years of age and older:

- Peel off protective backing and apply sticky side to affected area. Carefully remove backing from patch
- Should be used up to 8 hours
- Should be used no more than 3 to 4 times daily

Children under 12 years of age: Consult a doctor.

Purpose

Topical Analgesic

Warnings

KEEP OUT OF REACH OF CHILDREN.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

3% MENTHOL PLUS 0.083% CAPSAICIN PAIN RELIEF PATCH (2 PATCHES/POUCH)

pain relief patch, pain relief strip patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84205-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.83 mg in 1 g
MENTHOL, (+)- (UNII: C6B1OE8P3W) (MENTHOL, (+)- - UNII:C6B1OE8P3W)	MENTHOL, (+)-	0.03 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DMDM HYDANTOIN (UNII: BYR0546TOW)	
TARTARIC ACID (UNII: W4888I119H)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
KAOLIN (UNII: 24H4NWX5CO)	
ALCOHOL 95% (UNII: 7528N5H79B)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84205-007-00	8.5 g in 1 POUCH; Type 0: Not a Combination Product	05/16/2024	
2	NDC:84205-007-01	24 in 1 BOX	05/16/2024	
2	NDC:84205-007-00	8.5 g in 1 POUCH; Type 0: Not a Combination Product		

EXTRA STRENGTH PAIN RELIEF

HOT PATCH

FAST-ACTING PAIN RELIEF

For fast relief of minor aches and pains due to:

- Arthritis
- Strains
- Bruises
- Sprains

2 Patches
3.15 in x 4.72 in
(8 cm x 12 cm)

Drug Facts

Active Ingredients (in each gram)	Purpose
Menthol 30 mg	Topical Analgesic
Capsaicin 0.83 mg	Topical Analgesic

Uses
Temporarily relieves minor pain associated with:
• arthritis • simple backache • bursitis • tendonitis • muscle strains • bruises • cramps

WARNINGS: EXTERNAL USE ONLY

When using this product • use only as directed • do not bandage tightly or use with a heating pad
• avoid contact with eyes and mucous membranes • do not apply to wounds or damaged skin.

STOP USE and ask a doctor • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days • redness is present • skin irritation develops

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 (1-800-222-1232) immediately.

DIRECTIONS
Adults and Children 12 years of age and older:
• Partially peel back protective film and apply exposed patch to site of pain. Carefully remove remaining film while pressing patch to skin for secure adhesions
• Apply to affected area not more than 3 to 4 times daily
Children under 12 years of age: DO NOT use without consulting a doctor.

Other information
• store at room temperature 68° to 77°F (20 to 25°C)

Inactive Ingredients
Glycerin, Sodium Polycrylate, Dihydroxyaluminum Aminoacetate Anhydrous, Edetate Disodium, Kaolin, Carbomer, Carboxymethylcellulose Sodium, Purified Water, Tartaric Acid, POVIDONE K90, DMDM Hydantoin, Alcohol 95%, Polysorbate 80, Propylene Glycol

Manufacturer
Koolcare Technology Co., Ltd
Wenlv Healthcare Park, No. 18, Zhenbei Road, Xinyi city,
Jiangsu province, China 221400

LOT:
EXP:



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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	05/16/2024	

5% MENTHOL PAIN RELIEF PATCH (1 LARGE PATCH/POUCH)

pain relief patch patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84205-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, (+)- (UNII: C6B10E8P3W) (MENTHOL, (+)- - UNII:C6B10E8P3W)	MENTHOL, (+)-	0.05 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALCOHOL 95% (UNII: 7528N5H79B)	
TARTARIC ACID (UNII: W4888I119H)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
KAOLIN (UNII: 24H4NWX5CO)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	

Product Characteristics

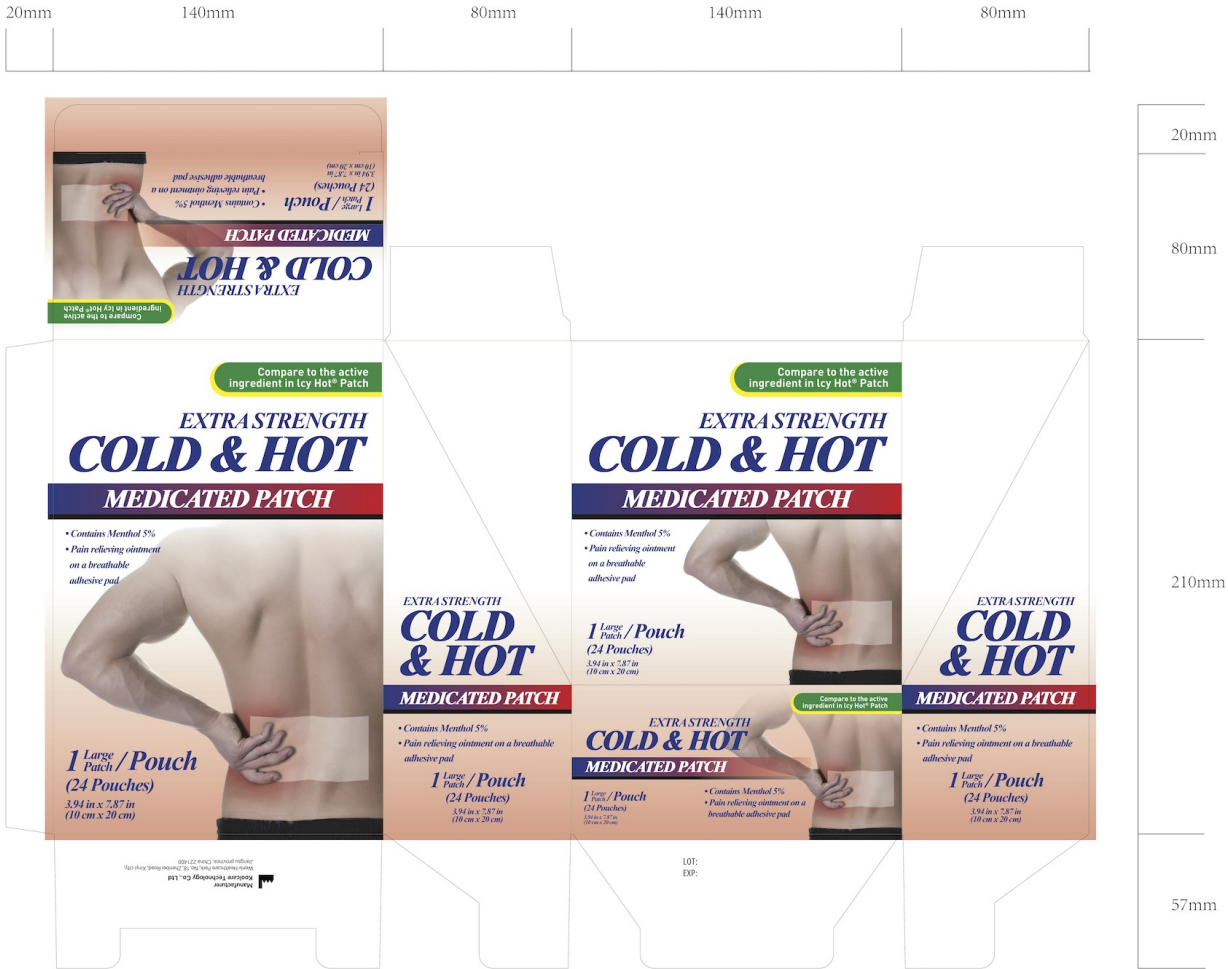
Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84205-008-00	19 g in 1 POUCH; Type 0: Not a Combination Product	05/16/2024	
2	NDC:84205-008-01	24 in 1 BOX	05/16/2024	
2	NDC:84205-008-00	19 g in 1 POUCH; Type 0: Not a Combination Product		

140x80x210mm

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	05/16/2024	

5% MENTHOL PAIN RELIEF PATCH (2 PATCHES/POUCH)

pain relief patch patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84205-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, (+)- (UNII: C6B10E8P3W) (MENTHOL, (+)- - UNII:C6B10E8P3W)	MENTHOL, (+)-	0.05 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C00X)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TARTARIC ACID (UNII: W4888I119H)	
KAOLIN (UNII: 24H4NWX5CO)	
ALCOHOL 95% (UNII: 7528N5H79B)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

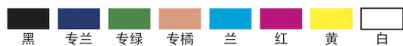
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84205-006-00	8.5 g in 1 POUCH; Type 0: Not a Combination Product	05/16/2024	
2	NDC:84205-006-01	24 in 1 BOX	05/16/2024	
2	NDC:84205-006-00	8.5 g in 1 POUCH; Type 0: Not a Combination Product		

Drug Facts

Active Ingredient	Purpose
Menthol 5%	Topical analgesic
Uses	
Temporarily relieve minor pain associated with: • arthritis • simple backache • muscle strains • bursitis • tendonitis • strains • bruises • cramps	
WARNINGS	
For external use only.	
When using this product: • use only as directed • do not bandage tightly or use with a heating pad • avoid contact with eyes and mucous membranes • do not apply to wounds or damaged skin.	
Stop use and ask a doctor if: • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days • redness is present • skin irritation develops.	
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 older: • peel off protective backing and apply sticky side to affected area • carefully remove backing from patch • should be used up to 8 hours • should be used no more than 3 times a day	
Children under 12 years of age: consult a doctor	
Other information • store at room temperature 68° to 77°F (20° to 25°C)	
Inactive ingredients Glycerin, Sodium Polyacrylate, Dihydroxyaluminum Aminoacetate Anhydrous, Edetate Disodium, Kaolin, Carbomer, Carboxymethylcellulose Sodium, Purified Water, Tartaric Acid, POVIDONE K90, DMDM Hydantoin, Alcohol 95%, Polysorbate 80	

Manufacturer
Koolcare Technology Co., Ltd
Wenlv Healthcare Park, No.18, Zhenbei Road, Xinyi city,
Jiangsu province, China 221400

LOT:
EXP:



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	05/16/2024	

0.025% CAPSAICIN PATCH (2 PATCHES/POUCH) 82632

capsaicin pain relief patch, capsaicin pain relief strip patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84205-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
KAOLIN (UNII: 24H4NWX5CO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
TARTARIC ACID (UNII: W4888I119H)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84205-005-00	6.65 g in 1 POUCH; Type 0: Not a Combination Product	06/16/2024	
2	NDC:84205-005-01	24 in 1 BOX	06/16/2024	
2	NDC:84205-005-00	6.65 g in 1 POUCH; Type 0: Not a Combination Product		

Compare to the active ingredient in Salonpas® - Hot Capsicum Patch®

TOPICAL ANALGESIC

CAPSAICIN HEAT PATCH

Temporary Relief of Minor Aches & Pains of Muscles & Joints Associated with:

Arthritis
Backaches
Bruises
Strains
Sprains

2 Patches/Pouch
5.12 IN x 7.09 IN
(13cm x 18cm)

Compare to the active ingredient in Salonpas® - Hot Capsicum Patch®

TOPICAL ANALGESIC

CAPSAICIN HEAT PATCH

Drug Facts

Active Ingredient	Purpose
Capsaicin Extract Capsaicin 0.025%	Topical Analgesic

Uses
For temporary relief of minor aches and pains of muscles & joints associated with:
• Simple Backache • Arthritis • Strains • Bruises • Sprains

WARNINGS: EXTERNAL USE ONLY

DO NOT USE
• on wounds or damaged skin
• with a heating pad
• with or at the same times as other external analgesic
• if you are allergic to any ingredients of this product

When using this product
• do not use otherwise than as directed
• avoid contact with the eyes, mucous membranes or rashes
• 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
• rash, itching or excessive skin irritation develops
• conditions worsen
• symptoms persist for more than 7 days
• symptoms clear up and occur again within 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 (1-800-222-1222) immediately.

DIRECTIONS
Adults and Children 12 years of age and over:
• Clean and dry affected area
• Remove patch from film
• Apply to affected area not more than 3 to 4 times daily
• Remove patch from skin after at most 8 hours of application
Children under 12 years of age: Consult a doctor.

Other Information
• Avoid storing product in direct sunlight
• Protect product from excessive moisture

Inactive Ingredients
Glycerin, Sodium Polyacrylate, Dihydroxyaluminum Aminoacetate Anhydrous, Edetate Disodium, Kaolin, Propylene Glycol, Polyisobutyl Methacrylate, Carbomer, Purified Water, POVIDONE K90, Tartaric Acid, DMDM Hydantoin

Manufacturer
Koolcare Technology Co., Ltd
Wenlu Healthcare Park, No. 18, Zhenbei Road, Xinyi city,
Jiangsu province, China 221400

LOT:
EXP:

255mm

180mm

黑 专兰 专绿 专红 兰 红 黄 专底 白

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	05/16/2024	

Labeler - Koolcare Technology Co., Ltd (602479389)

Registrant - Koolcare Technology Co., Ltd (602479389)

Establishment

Name	Address	ID/FEI	Business Operations
Koolcare Technology Co., Ltd		602479389	manufacture(84205-005, 84205-006, 84205-007, 84205-008)

Revised: 8/2024

Koolcare Technology Co., Ltd