

PAINKOOLERS- menthol, capsaicin patch
Pure Source, LLC

PainKoolers Pain Relief Patch

DRUG FACTS

ACTIVE INGREDIENTS:

Menthol 5.00%

Capsaicin 0.0375%

Purpose

Analgesic/Counterirritant

External Analgesic

USES:

For the temporary relief of minor aches and pains of the muscles and joints associated with simple backache, arthritis, sprains, bruises and strains.

WARNINGS:

- For external use only. Use only as directed. Avoid contact with eyes and mucous membranes.
- Do not cover with bandage.

Do not use

- on wounds or damaged skin.
- in combination with any other external analgesic products.
- in combination with any external heat source.
- on irritated or broken skin, or use in combination with any bandage, wrap, stocking or similar device or garment.
- if you are allergic to Menthol.

Keep out of reach of children.

Consult physician for children under 12.

Stop use and ask a doctor

- if conditions worsen, symptoms persist for more than 7 days or clear up and occur again within a few days.
- if rash, itching or excessive skin irritation occurs.

DIRECTIONS:

- Adults and children 12 years and over apply to affected area; change patch 1 to 2 times daily.
- Children under 12 years, consult physician before use.
- How to apply:
- Clean and dry affected area
- Cut open pouch and remove patch
- Remove protective film and apply directly to the area of pain
- Apply to affected area not more than 3 times daily
- Wash hands with soap after applying patch
- Reseal pouch containing unused patches

OTHER INGREDIENTS:

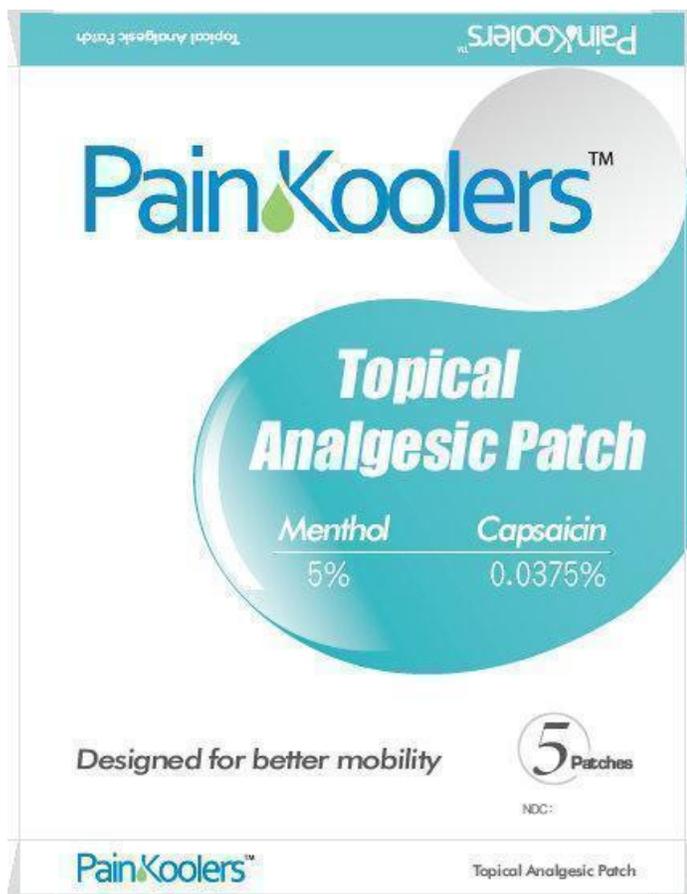
Water, Glycerine, Sodium Polyacrylate, Polysorbate 80Barbadesis Leaf (Aloe Vera Gel) Juice, EDTA Disodium salt, Diazolidinyl Urea, Methylparaben, Iodopropynyl Butylcabamate, Propylparaben.

Store

below 25 degrees. Avoid direct sunlight.

Product Label

PainKoolers Topical Analgesic patch Menthol 5% Capsaicin 0.0375% Designed for better mobility 5 Patches



PainKoolers™

Topical Analgesic Patch

Menthol 5% Capsaicin 0.0375%

Designed for better mobility

5 Patches

NDC: 65121-828

PainKoolers™ Topical Analgesic Patch

PainKoolers™ Patch

DRUG FACTS:

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Menthol	5.00%	Analgesc/Counterirritant
Capsaicin	0.0375%	External Analgesic

USES:
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- Do not cover with bandage.
- Do not use on wounds or damaged skin.
- Do not use in combination with any other external analgesic products.
- Avoid contact with eyes and mucous membranes.
- Do not use in combination with any external heat source.
- Do not use on irritated or broken skin, or use in combination with any bandage, wrap, stocking or similar device or garment.
- Keep out of reach of children. Consult physician for children under 12.
- Do not use if you are allergic to Menthol.
- Stop use and ask a doctor if conditions worsen, symptoms persist for more than 7 days or clear up and occur again within a few days.
- or Rash, itching or excessive skin irritation occurs.

DIRECTIONS:

- Adults and children 12 years and over apply to affected area; change patch 1 to 2 times daily.
- Children under 12 years, consult physician before use.
- How to apply:
 - Clean and dry affected area
 - Cut open pouch and remove patch
 - Remove protective film and apply directly to area of pain
 - Apply to affected area not more than 3 times daily
 - Wash hands with soap after applying patch
 - Reveal pouch containing unused patches

OTHER INGREDIENTS:
Water, Glycerin, Sodium Polycrylate, Polysorbate 80, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, EDTA Disodium salt, Diazolidinyl Urea, Methylparaben, Iodopropynyl Butylcarbamate, Propylparaben.

Store below 25 degrees. Avoid direct sunlight.

Distributed by:
PainSource INC.
920 NW 175th Street, Miami, FL 33177, USA



PAINKOOLERS

menthol, capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65121-828
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g in 100 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.0375 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65121-828-05	5 in 1 BOX	02/10/2017	
1		8 g 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 Drug	M017	12/30/2014	

Labeler - Pure Source, LLC (080354456)

Revised: 11/2023

Pure Source, LLC