

PAINKOOLERS TOPICAL ANALGESIC PATCH- menthol and capsaicin patch
GA Health and Beauty (FOSHAN) Co., Ltd

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.

PainKoolers Topical Analgesic Patch

ACTIVE INGREDIENTS:

Menthol 5.00%

Capsaicin 0.05%

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.
- 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.

Keep out of reach of children.

Consult Physician for children under 12.

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


Reseal pouch containing unused patches

OTHER INGREDIENTS:

Water, Glycerine, Sodium Polyacrylate, Polysorbate 80, Aloe Barbadesis Leaf (Aloe Vera Gel)

Juice, EDTA Disodium salt, Diaxolidinyl Urea, Methylparaben, Iodopronyl Butylcarbamate, Propylparaben.

Package Label




PainKoolers™

Topical Analgesic Patch


Menthol	Capsaicin
5%	0.05%

Contoured Style For Perfect Fit



NDC:

PainKoolers™ Patch

DRUG FACTS:		
ACTIVE INGREDIENTS:		
Menthol	5.00%	Analgesic/Counterirritant
Capsaicin	0.05%	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.		
<ul style="list-style-type: none"> • 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:		
<ul style="list-style-type: none"> • 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:		
<ul style="list-style-type: none"> - Clean and dry affected area - Cut open pouch and remove patch - Remove protected 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 - Reseal pouch containing unused patches 		
OTHER INGREDIENTS:		
Water, Glycerine, Sodium Polyacrylate, Polysorbate 80, Aloe Barbadesis Leaf (Aloe Vera Gel) Juice, EDTA Disodium salt, Diazolidinyl Urea, Methylparaben, Iodopronyl Butylcarbamate, Propylparaben.		
<p>Manufactured by GA Health and Beauty Co, Ltd F3, 9Fuzhong Road, Guan Tian, Longjiang 528218, Shunde, Foshan City, Guang Dong, China</p> <p style="text-align: center;">www.gahealth-beauty.com</p>		
		 <p style="font-size: small;">0 616983 255513</p>

PAINKOOLERS TOPICAL ANALGESIC PATCH

menthol and capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70118-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g in 1 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.05 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (250000 MW) (UNII: 05115JN12J)	
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:70118-001-05	5 in 1 POUCH		
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 not final	part348	09/21/2015	

Labeler - GA Health and Beauty (FOSHAN) Co., Ltd (544333811)

Revised: 9/2015

GA Health and Beauty (FOSHAN) Co., Ltd