

PAINKOOLERS TOPICAL ANALGESIC- menthol, unspecified form, capsaicin gel
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

DRUG FACTS:

ACTIVE INGREDIENTS:

Menthol 5.00%

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.

- **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 or amenthol

- **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 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

INACTIVE INGREDIENTS:


Purified Water,Glycerin,Polyvinyl Alcohol,Sodium Polyacrylate,Propylene Glycol,Polysorbate 80,Sorbitan Stearate,Aloe Barbadensis leaf (Aloe Vera Gel) Juice, Aanica Montana Extract, Rosemary Oil,Tartaric Acid,Dihydroxyaluminum Aminoacetate,Titanium Dioxide,Kaolin,Glydant Plus Liquid.

Package Labeling:



The image shows the packaging for PainKoolers Topical Analgesic Patches. The main part of the package is yellow with a large white circle in the center. Inside the circle, the text "Topical Analgesic Patch" is written in a bold, sans-serif font. Below this, the ingredients "Menthol 5%" and "Capsaicin 0.05%" are listed. The PainKoolers logo is at the top left, and a circular icon with the number "5" and the word "Patches" is at the bottom right. The text "Contoured Style For Perfect Fit" is at the bottom left.

PainKoolers™ Patch

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Capsaicin	0.05%
External Analgesic	
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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 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:	
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Distributed by GA Health and Beauty Co. Ltd 1213 WingOn Plaza, 62 Mody Road, Kowloon, Hong Kong www.gahealth-beauty.com Made in China	
 Ref: 5551	

PAINKOOLERS TOPICAL ANALGESIC

menthol, unspecified form, capsaicin gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70 118-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)			MENTHOL, UNSPECIFIED FORM	5 g in 100 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)			CAPSAICIN	0.05 g in 100 g
Inactive Ingredients				
Ingredient Name				Strength
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYVINYL ALCOHOL (UNII: 532B59J990)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
ARNICA MONTANA (UNII: O80TY208ZW)				
ROSEMARY OIL (UNII: 8LGU7VM393)				
TARTARIC ACID (UNII: W4888I119H)				
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
KAOLIN (UNII: 24H4NWX5CO)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70118-002-05	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	11/21/2015	

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

Establishment

Name	Address	ID/FEI	Business Operations
GA Health and Beauty (FOSHAN) Co., Ltd		544333811	repack(70118-002) , relabel(70118-002)