

PAIN-RELIEVING ABDOMINAL BINDER- pain-relieving abdominal binder cloth
The Marena Group LLC

Relieving Abdominal Binder 84721-001-01

Active ingredient

Capsaicin (synthetic) 0.16%

Purpose

Topical Analgesic

Uses

For the temporary relief of minor aches and pains of muscles associated with: bruises.

Warnings

For external use only.

Do not use

- If you are allergic to any ingredients in this product or to chili peppers, contact a doctor before use (allergy alert)
- On wounds or damaged skin
- With, or at the same time as, other external analgesic products
- With a heating pad

When using this product

- You may experience a burning sensation which is normal and related to the way the product works (with regular use, this sensation generally diminishes)
- Do not use immediately before or after activities such as swimming, showering, sunbathing or intense exercise
- Use only as directed
- Avoid contact with eyes and mucous membranes or rashes

Stop use and ask doctor if

- Condition worsens or persists for more than 7 days, or if symptoms clear up and occur again within a few days
- Rash, itching or excessive skin irritation develops

If pregnant or breastfeeding

Consult a healthcare professional before use.

Keep out of reach of children

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

Directions

- Clean and dry affected area before use
- Remove product from packaging, open binder and place on abdomen making sure active ingredient is on the affected area (active ingredient is indicated by the lighter colored yarn on the inside of binder)
- Close binder by gently yet firmly pressing the closures together
- Wash hands after handling binder
- Maximum use of 10 hours per day
- Do not wear more than 6 days straight without doctor consent
- Hand wash separately from other clothes, with closure engaged

Other information

- Avoid storing product in direct sunlight
- Protect product from excessive moisture
- Active ingredient remains in effect for up to 15 washes

Inactive ingredient

acrylate copolymer

Principal Label





9" Pain-Relieving Abdominal Binder

Style: AICAB09

This 9-Inch Pain-Relieving Abdominal Binder combines soothing capsaicin with the comfortable and supportive stretch material of our trusted binders, providing up to 10 hours of pain relief.

- Capsaicin-infused fabric for extended pain relief
- Adjustable closure for optimal fit
- Can be worn up to 10 hours per day
- Fits up to a 40-inch waist
- Can be washed up to 15 times before capsaicin expires

Color: Black

94% polyester 5% nylon and 1% spandex

Drug Facts	
Active Ingredient: (1 Binder)	Purpose
Capsaicin (Synthetic) 0.16% Topical Analgesic	
Uses: <ul style="list-style-type: none">• For the temporary relief of minor aches and pains of muscles associated with: bruises.	
Warnings: For external use only	
Do Not Use <ul style="list-style-type: none">• If you are allergic to any ingredients in this product or to chili peppers, contact a doctor before use (allergy alert)• On wounds or damaged skin• With, or at the same time as, other external analgesic products• With a heating pad	
When using this product <ul style="list-style-type: none">• You may experience a burning sensation which is normal and related to the way the product works (with regular use, this sensation generally diminishes)• Do not use immediately before or after activities such as swimming, showering, sunbathing or intense exercise• Use only as directed• Avoid contact with eyes and mucous membranes or rashes	
Stop use and ask doctor if: <ul style="list-style-type: none">• Condition worsens or persists for more than 7 days, or if symptoms clear up and occur again within a few days• Rash, itching or excessive skin irritation develops	
If pregnant or breastfeeding <ul style="list-style-type: none">• Consult a healthcare professional before use	
Keep out of reach of children <ul style="list-style-type: none">• If swallowed, get medical help or contact a Poison Control Center right away	
Directions: <ul style="list-style-type: none">• Clean and dry affected area before use• Remove product from packaging, open binder and place on abdomen making sure active ingredient is on the affected area (active ingredient is	

indicated by the lighter colored yarn on the inside of binder)

- Close binder by gently yet firmly pressing the closures together
- Wash hands after handling binder
- Maximum use of 10 hours per day
- Do not wear more than 6 days straight without doctor consent
- Hand wash separately from other clothes, with closure engaged

Other information:

- Avoid storing product in direct sunlight
- Protect product from excessive moisture
- Active ingredient remains in effect for up to 15 washes

If discomfort occurs,
contact your physician.

See care instructions inside.

81-0444-00

PAIN-RELIEVING ABDOMINAL BINDER

pain-relieving abdominal binder cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84721-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.16 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	

Product Characteristics

Color		Score	
Shape		Size	229mm
Flavor		Imprint Code	

Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84721-001-01	1 g in 1 POUCH; Type 0: Not a Combination Product	09/11/2024	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	09/11/2024		

Labeler - The Marena Group LLC (929793305)

Registrant - The Marena Group LLC (929793305)

Establishment			
Name	Address	ID/FEI	Business Operations
Textile-Based Delivery Inc		079309716	api manufacture(84721-001)

Establishment			
Name	Address	ID/FEI	Business Operations
The Marena Group LLC		929793305	label(84721-001) , pack(84721-001)

Revised: 9/2024

The Marena Group LLC