PAINBLOC24- capsaicin 0.25% solution Vizuri Health Sciences LLC

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.

PainBloc24

Active Ingredient

Capsaicin 0.25%

Purpose

Topical Analgesic

Uses

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

- Arthritis
- Simple backache
- Muscle strains
- Bruises
- Sprains

Warnings

For external use only

When using this product

- Use only as directed
- Do not bandage tightly or cover treated area
- Do not use with heating pad
- Avoid contact with eyes and mucous membranes
- Do not apply to wounds, damaged, broken or irritated skin
- Do not expose the area treated with product to heat or direct sunlight
- If using before exercise, showering or swimming, apply, wait 30 minutes, then wash off before participating
- A temporary burning sensation and/or redness may occur upon application. This is normal and generally stops after a few days of use

Stop use and ask a doctor if

- Severe burning sensation occurs
- You experience difficulty breathing or swallowing
- Condition worsens

- Redness persists, spreads or becomes tender
- Irritation develops
- Symptoms last more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding, ask 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

Adults over 18 years:

- Apply by holding Pain Pen straight down and press tip repeatedly on to affected area until liquid flows. Then dab sparingly.
- Allow to dry
- Repeat application, as needed, every 12 to 24 hours
- Do not use more than twice a day
- Wash hands with soap and water after each application. If applying to hand, wait 30minutes, then wash with soap and cold water after each application.
- If soap does not completely remove all product residues, try using skin or mineral oil.
- May take several days to reach full effect

Inactive Ingredients

Alcohol, Diethylene Glycol Monoethyl Ether, Hyaluronate Sodium, Polysorbate 80, Pramoxine HCl, Propylene Glycol, Water

Questions

Call 855-438-3944

Distributed by Vizuri Consumer Healthcare Fairfax, VA 22033 U.S.A.

PRINCIPAL DISPLAY PANEL - 12 mL Bottle Carton





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COLORS 4 COLOR PROCESS
CYAN MAGENIA YELLOW BLACK

FONTS
Akhand Black
Helvetica Neue LT Std 75 Bold
Akhand Bold
Roboto Condensed Light
Akhand

LINKED FILES

Pen2 psd PENApplicator Illustration_Final_layered eps

capsaicin 0.25% solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71226-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
l	CAPSAICIN (LINII: S07044R17M) (CAPSAICIN - LINII:S07044R17M)	CAPSAICIN	2.5 mg in 1 ml

Inactive Ingredients

Ingredient Name
Strength

ALCOHOL (UNII: 3K9958V90M)

DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)

HYALURONATE SODIUM (UNII: YSE9PPT4TH)

POLYSORBATE 80 (UNII: 6OZP39ZG8H)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

WATER (UNII: 059QF0KO0R)

PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5)

Item Code Package Description Marketing Start Date

1 NDC:71226001-06 1 in 1 CARTON 11/05/2019

1 2 mL in 1 BOTTLE, WTH APPLICATOR; 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	11/05/2019		

Labeler - Vizuri Health Sciences LLC (052129499)

Revised: 1/2022 Vizuri Health Sciences LLC