

**PAINBLOC- capsaicin 0.25% liquid**  
**Denison Pharmaceuticals, 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.*

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**PainBloc**

**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 30 minutes, 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

**PRINCIPAL DISPLAY PANEL - 12 mL Bottle Carton**



**NEW!**

## PAIN BLOC 24

### 24 HOUR ARTHRITIS PAIN RELIEF

SERIOUS MEDICINE FOR YOUR ARTHRITIS PAIN

The only OTC topical pain reliever that can help provide 24hr arthritis pain relief with as little as one application every day.

- Patented formula helps block arthritis joint pain at the source of the pain signal
- Deactivates certain nerve fibers that transmit pain signals to the brain
- Clinically shown to provide long-lasting relief\*
- Use for a week and pain relief will last up to a month!

**Take the PainBloc24® Challenge:**  
Try it for a week and tell us about it at [www.PainBloc24.com](http://www.PainBloc24.com)

**IMPORTANT: PLEASE READ AND KEEP THIS IMPORTANT INFORMATION.**

If this is your first time using PainBloc24® or if you have sensitive skin, test on a small area prior to regular usage.

- Use daily as directed.
- Relief builds and reaches full effect after several days of use.
- Mild to moderate warming is a sign that PainBloc24® is working. Warming will decline with use.
- Wash hands with soap and cold water after each use. If applying to hands, wait 30 minutes, then wash with soap and cold water after each use.
- Don't get in your eyes.
- Keep out of reach of children.

For external use only.

**What is capsaicin?** Capsaicin is a naturally occurring substance found in chili peppers. It is generally regarded as safe and effective by the Food and Drug Administration when used as a topical analgesic to help relieve arthritis or muscular pain.

**What is PainBloc24®?** PainBloc24® is a topical pain reliever made with the highest concentration of pharmaceutical-grade capsaicin allowed by the FDA without a prescription. Its patented NeuroMax® formula is made of several safe, non-active ingredients that support the tolerability and effectiveness of the capsaicin.

\*Clinical study conducted in osteoarthritis knee pain

**Drug Facts**

**Active Ingredient**  
Capsaicin 0.25%  
Topical Analgesic

**Purpose**  
Use for the temporary relief of minor aches and pains of muscle aches • bruises • sprains • muscle strains • blisters • warts • arthritis • sunburn • headache

**Warnings**  
For external use only.  
When using this product:  
• Do not use on open wounds or cuts.  
• Do not use on the face, neck, or chest.  
• Do not use on the hands if you are wearing gloves.  
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**Directions**  
Apply to the affected area. Rub gently until the product is absorbed. Wash hands with soap and cold water after each use. Do not use on the hands if you are wearing gloves. Do not use on the hands if you are wearing gloves.

**Other Important Information**  
• Do not use on the hands if you are wearing gloves.  
• Do not use on the hands if you are wearing gloves.  
• Do not use on the hands if you are wearing gloves.

**Questions**  
Call 1-800-438-3344  
For more information, visit [www.PainBloc24.com](http://www.PainBloc24.com)

**Manufacturer**  
Vizual, Inc.  
11111 1st Avenue, Suite 100  
Houston, TX 77036



1800 Lyndon Parkway  
Suite 820  
Plymouth, MA 01961  
Office: (513) 344-3300  
mackey@macys.com

**JOB INFORMATION**

Client: Allus  
Job No: 6016  
File Name: 6016 PainBloc24 E1944R1 Carton V2.ai  
Program: Illustrator CC  
Date: 07-24-13

**COLORS:**  
4 COLOR PROCESS  
CYAN MAGENTA YELLOW BLACK

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

**LINKED FILES**  
Pan2.psd  
PENApplicator Illustration\_Final\_layered.eps

capsaicin 0.25% liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0295-9029
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	2.5 mg in 1 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0295-9029-60	1 in 1 CARTON	03/09/2020	
1		12 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348	03/09/2020	

**Labeler** - Denison Pharmaceuticals, LLC (001207208)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Denison Pharmaceuticals, LLC		001207208	manufacture(0295-9029)