

**PAINBLOC24 PROWOMEN WOMENS DISCOMFORTS MENTHOL PAIN AND SLEEP PATCH- menthol 6% patch  
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.*

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**Drug Facts**

**Active Ingredient**

Menthol unspecified 6%

**Purpose**

Topical Analgesic

**Uses**

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

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

**Warnings**

**For external use only**

**When using this product**

- use only as directed
- consult your doctor before use if using any medications or supplements that contain any of these same ingredients
- do not bandage tightly
- 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 use at the same time as other topical analgesics

**Stop use and ask a doctor if**

- condition worsens
- redness persists, spreads or becomes tender
- symptoms last more than 7 days or clear up and occur again within a few days
- you experience burning swelling or blistering where applied

**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:**

- clean and dry affected area
- trim excessive hair for better adhesion
- open pouch and remove patch
- remove backing from patch by grasping both ends and pulling backing apart
- peel off one half of backing and place patch onto affected area
- peel off other half of backing and press and smooth onto skin
- use patch as needed for up to 8 hours. Do not remove when wet or directly after showering or bathing. Allow patch to dry and then slowly remove.
- use one patch at a time for up to 8 hours

**Children under 18 years:** consult a doctor

### **Inactive Ingredients**

Acrylic adhesive, arnica montana flower extract, chamomile, d-limonene, dipropylene glycol, gamma-aminobutyric acid (GABA), hemp oil, l-theanine, lavender, magnesium chloride, melatonin, passionflower, polysorbate 80, tocopheryl acetate (Vitamin E), white curcumin

### ***Questions***

Call 855-438-3944

### **Other Information**

Store in a cool, dry place at room temperature

### **Product label**



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**JOB INFO:**  
CLIENT: Vizuri HealthCare  
JOB: Real Patch Box  
FILE: PainBloc24 Shep Curve\_11-15-2021.at  
DATE: 11/15/2021

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**COLORS:**  
CMYK █ █ █ █  
PMS █ █ █ █

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13.125"

6.5625"



0.125"

BACK PANEL HAS EYE MARK

0.375"

**PAINBLOC24 PROWOMEN WOMENS DISCOMFORTS MENTHOL PAIN AND SLEEP PATCH**

menthol 6% patch

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71226-004
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	6 g

## Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CHAMOMILE (UNII: FGL3685T2X)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
.GAMMA.-AMINOBUTYRIC ACID (UNII: 2ACZ6IPC6I)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
THEANINE (UNII: 8021PR16QO)	
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
MELATONIN (UNII: JL5DK93RCL)	
PASSIFLORA INCARNATA FLOWER (UNII: K8F3G29S6Z)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CURCUMIN (UNII: IT942ZTH98)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71226-004-01	1 in 1 CARTON	01/25/2022	
1		5 in 1 POUCH; 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	01/25/2022	

**Labeler** - VIZURI HEALTH SCIENCES LLC (052129499)

## Establishment

Name	Address	ID/FEI	Business Operations
Shawsheen Rubber Co.		001051275	manufacture(71226-004)

Revised: 1/2022

VIZURI HEALTH SCIENCES LLC