PAINPATROL PROFESSIONAL PAIN RELIEF- menthol, unspecified form gel SmartScience Laboratories, Inc.

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.

PainPatrol[™] Professional Pain Relief

Drug Facts

Active Ingredient

Natural Menthol, USP (8.5%)

Purpose

Topical Analgesic

Uses

Temporarily relieves foot, ankle and leg pain associated with:

- arthritis
- muscle aches
- muscle strains
- muscle sprains
- joint pain

Warnings

For external use only: Flammable: Keep away from excessive heat or open flame.

• Ask a doctor before use is you have sensitive skin or if you are taking any blood thinners,

When using this product

Do not use on wounds or irritated skin

- Do not bandage tightly or usewith a heating pad
- Wash hands after use with cool water
- If pregnant or breast feeding, ask a health professional before use
- **Keep out of reach of children.** If accidentally swallowed, contact a doctor or poison control center immediately
- **Stop use and ask a doctor** if condition worsens or if pain persists for more than 7 days, or clears up, then reoccurs within a few days.

Directions

Use only as directed

- Do not use on children under 12 years of age.
- Roll onto affected area no more than four times daily. Shake well before each use.

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Arnica Montana Extract, Boswellia Serrata Extract, Camphor, Carbomer, Chondroitin Sulfate, Glucosamine Sulfate, Glycerin, Ilex Paraguarensis Extract, Isopropyl Alcohol, Methyl Paraben, Methylsulfonylmethane, Peppermint Oil, Polysorbate 20, Propylene Glycol, Triethanolamine, Purified Water

Other Information

Questions or comments?

Call (877) 383-2334.

Store in a cool dry place with the cap tightly closed. Note: Because this product contains natural ingredients, color may vary.

Manufactured by: SmartScience Laboratories, Inc 13760 Reptron Blvd., Tampa, FL 33626

PRINCIPAL DISPLAY PANEL - 88 ML Bottle Label

Clinical Strength Menthol Formula

PainPatrol[™] Professional Pain Relief

Pain Relief for arthritis, joints and muscles. Also contains Glucosamine • Chondroitin • Arnica • Boswellia

No Mess Applicator. 3FL OZ (88ML)

Clinical Strength Menthol Formula

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Made in USA. Manufactured by: SmartScience Laboratories, Inc 13760 Reptron Blvd., Tampa, FL 33626	20 Years of Pain Relief Products. NDC # 64479-200-10 No Animal Testing.	Other Information: Questions or comments? Call (877) 383-2334. Store in a cool dry place with the cap tightly closed. Note: Because this product contains natural ingredients, color may vary.	<i>Inactive Ingredients:</i> Aloe Barbadensis Leaf Extract, Arnica Montana Extract, Boswellia Serrata Extract, Camphor, Carbomer, Chondroltin Sulfate, Glucosamine Sulfate, Glycerin, Ilex Paraguarensis Extract, Isopropyl Alcohol, Methyl Paraben, Methylsulfonylmethane, Peppermint Oli, Polysorbate 20, Propylene Glycol, Triethanolamine, Purified Water	 Directions: Use only as directed • Do not use on children under 12 years of age. • Roll onto affected area no more than four times daily. Shake well before each use. 	 Warnings: For external use only: Flammable: Keep away from excessive heat or open flame. Ask a doctor before use is you have sensitive skin or if you are taking any blood thinners, When using this product: Do not use on wounds or irritated skin • Do not bandage tightly or usewith a heating pad • Wash hands after use with cool water • If pregnant or breast feeding, ask a heath professional before use • Keep out of reach of children. If accidentally swallowed,contact a doctor or poison control center immediately • Stop use and ask a doctor if condition worsens or if pain persists for more than 7 days, or clears up, then reoccurs within a few days. 	Natural Menthol, USP (8.5%)Topical Analgesic Uses: Temporarily relieves foot, ankle and leg pain associated with: • arthritis • muscle aches • muscle strains • muscle sprains • joint pain	Active Ingredient Purpose	Drug Facts	Shake well before each use.	Also contains Glucosamine • Chondroitin • Arnica • Boswellia

Pain Relief for arthritis, joints and muscles.

3FL OZ (88ML)

PAINPATROL PROFESSIONAL PAIN RELIEF

menthol, unspecified form gel

Product Information					
Product Type	HUMAN OTC DRUG Item Code (Source		e) NDC:64479-200		9-200
Route of Administration	TOPICAL				
Active Ingredient/Active Moi	ety				
Ing	redient Name		Basis of S	trength	Strength
Menthol, Unspecified Form (UNII: L7T10EIP3A) (Menthol, Unspecified Form - Menthol, UNII:L7T10EIP3A) Form				Menthol, Unspecified Form	
· •	ſ10EIP3A) (Menthol, Unspecified	Form -		pecified	85 mg in 1 mL
· •	[10 EIP3A) (Menthol, Unspecified	Form -		pecified	0
· •	[10 EIP3A] (Menthol, Unspecified	Form -		pecified	0
UNII:L7T10EIP3A)	(Menthol, Unspecified) (Menthol, Unspecified)	Form -		pecified	0
UNII:L7T10EIP3A)	Ingredient Name	Form -			in 1 mL
UNII:L7T10EIP3A)	Ingredient Name	Form -			in 1 mL
UNII:L7T10EIP3A) Inactive Ingredients ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 2	Ingredient Name (X) ZW)	Form -			in 1 mL
UNII:L7T10EIP3A) Inactive Ingredients ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 3 ARNICA MONTANA (UNII: 080 TY208	Ingredient Name () ZW) IQCO2M)	Form -			in 1 mL
UNII:L7T10EIP3A) Inactive Ingredients ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 3 ARNICA MONTANA (UNII: 080 TY208 INDIAN FRANKINCENSE (UNII: 4PW41	Ingredient Name () ZW) IQCO2M) 82A1ET)		Form		in 1 mL

GLUCO SAMINE SULFATE POTASSIUM CHLORIDE (UNII: 15VQ11166N)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:64479- 200-10	88 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	03/10/2019	
2	NDC:64479- 200-12	944 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/20/2020	
	200-12			

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	03/10/2019	

Labeler - SmartScience Laboratories, Inc. (035907919)

Revised: 2/2020

SmartScience Laboratories, Inc.