SALONPAS- camphor, menthol, methyl salicylate patch Bryant Ranch Prepack

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.

® Tablets

Active ingredients

Camphor 3.1%

Menthol 6.0%

Methyl salicylate 10.0%

Purpose

Topical analgesic

Uses

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

- arthritis
- simple backache
- strains
- bruises
- sprains

Warnings

For external use only

Allergy alert:

If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

Do not use

- on wounds or damaged skin
- with a heating pad
- if you are allergic to any ingredients of this product

When using this product

- use only as directed
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly

Stop use and ask a doctor if

- rash, itching or excessive skin irritation develops
- conditions worsen
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

Adults and children 12 years of age and over:

- clean and dry affected area
- remove patch from film
- apply to affected area not more than 3 to 4 times daily
- remove patch from the skin after at most 8-hour application

Children under 12 years of age: consult a doctor

Other information

- avoid storing product in direct sunlight
- protect product from excessive moisture

Inactive ingredients

mineral oil, perfume, polyisobutylene, styrene-isoprene-styrene block copolymer, synthetic aluminum silicate, terpene resin, titanium dioxide

Questions or comments?

Toll free **1-800-826-8861** www.salonpas.us

HOW SUPPLIED

NDC: 63629-8310-1: 20 Patchs in a POUCH

Salonpas Pain Relief Blister patch

Salonpas Pain Relief Blister patch

NA NA

52348/

Compare To

Salonpas Pain Relief Blister patch

Hisamitsu Pharmaceutical Co. Inc.

20

EXP MM/YY

NDC

6362983101

Store at room temp of 20°-25°C (68°-77°F)

Keep all drugs out of reach of children.



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SALONPAS

camphor, menthol, methyl salicylate patch

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63629-8310(NDC:46581-110)

TOPICAL, PERCUTANEOUS,

Route of Administration TRANSDERMAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) -CAMPHOR (SYNTHETIC) 21.56 mg UNII:5TJD82A1ET) MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL -MENTHOL, UNSPECIFIED 41.73 mg UNII:L7T10EIP3A) **FORM** METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID -METHYL SALICYLATE 69.55 mg UNII:O414PZ4LPZ)

Inactive Ingredients	
Ingredient Name	Strength

MINERAL OIL (UNII: T5L8T28FGP)	
ALUMINUM SILICATE (UNII: T1FAD4SS2M)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

l	Packaging						
	#	# Item Code Package Description		Marketing Start Date	Marketing End Date		
	1	NDC:63629- 8310-1	20 in 1 POUCH; Type 0: Not a Combination Product	02/22/2022			

Marketing Information					
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
part348	06/01/2015				
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date			

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment					
Name	Address	ID/FEI	Business Operations		
Bryant Ranch Prepack		171714327	REPACK(63629-8310), RELABEL(63629-8310)		

Revised: 2/2022 Bryant Ranch Prepack